FACTORS ASSOCIATED WITH DETERMINING CPT 92512 AS EXPERIMENTAL AND INVESTIGATIONAL AMONG THIRD-PARTY PAYORS

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ABSTRACT

FACTORS ASSOCIATED WITH DETERMINING CPT 92512 AS EXPERIMENTAL AND INVESTIGATIONAL AMONG THIRD-PARTY PAYORS

by Karen Parker Davidson

The healthcare reimbursement system is a complex framework for obtaining payment for services by licensed healthcare providers. Third-party payors have a direct impact on the utilization of healthcare services and policy by formulating clinical policy bulletins (CPBs) to justify the reimbursement and policy coverage of investigational and non-investigational products and services used by healthcare providers for their patients. CPBs explain the medical, dental, and pharmacy services third-party payors may or may not cover or require prior authorization for based on objective, credible sources, such as the scientific literature, guidelines, consensus statements and expert opinions. CPBs detail the services and procedures considered medically necessary, cosmetic, investigational, or experimental and unproven, what will and will not be covered. CPBs directing the plan of patient care are independent policies and vary from payor to payor.

By conducting content analysis of CPBs and interviews with stakeholders, this research examined clinical policies, bulletins, and literature to understand how third-party payors define U.S. Food and Drug Administration approved products and services as investigational versus non-investigational and the factors associated with the label. Specifically, the interview portion of the study obtained opinions of five subject matter experts (SMEs) through a set number of questions to uncover additional details about reimbursement and their opinion of the experimental and investigational label, as it relates to factors associated with coverage

determinations. The specific Current Procedural Technology (CPT) discussed will be 92512, nasal function study.

Of the more than 55 CPB professional and government documents included for content analysis, approximately 15 were included for review. The results in the study were related to factors associated with the label of experimental and investigational and how the label is interpreted for coverage determination by third-party payors. Of the 14 major commercial payors that cover more that 54% of the healthcare market, two of the top insurers and their policies listed CPT 92512 as experimental and investigational. Because the topic is under researched and published with limited literature, a qualitative method was conducted to better understand the investigational/experimental label. The interviews consisted of 11 questions among five groups of SMEs who have influence on, knowledge of, or use CPT 92515.

The conclusions found that although Medicare is the gold standard for reimbursement and coverage by commercial payors, payors will use their own criteria to create coverage determination in the form of CPBs and provide very limited information on how they come to their conclusion and definition of experimental and investigational. Furthermore, commercial, private payors provide few details and definitions as to what evidence meets their standards in order to convert and reverse the determination to one of coverage without restrictions or prior authorization. The challenges of the experimental and investigational label and the subjective determinations of commercial payors not only interfere with the delivery of healthcare and healthcare policy, but the attraction to enrollees to their benefit plans. It is anticipated that CPB coverage for CPT 92512 will consist of predictable and unpredictable components, such as the age of a CPB, the number of policy reviews, size of the third-party payor based on the number of

enrollees, and the quality of resources validating the CPB and the label of experimental and investigational.

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CHAPTER I

INTRODUCTION

The United States healthcare system utilizes reimbursement payment mechanisms varying in degrees of effectiveness to include fee-for-service, pay-for-performance, and capitation, which carry various strengths and weaknesses. Each reimbursement mechanism should account for any aspect of care, such as quality, complexity, and quantity of services. Within each reimbursement mechanism, regulatory and policy controls affect healthcare reimbursement by creating a driving force for how the U.S. Food and Drug Administration (FDA) approved medical technology and products are used by the healthcare providers, the amount paid towards their revenue cycle for the practice, and ultimately, patient care and outcomes (Centers for Medicare and Medicaid Services [CMS], 2018; FDA, 2019).

Many medical innovations, tests, and products, such as nasal measurements for nasal function studies, are a relevant part of clinical practice and should be medically coded and considered as a standard of practice for reimbursement for several reasons. Although FDA approved and reimbursed by CMS with a relative value unit (RVU) and a national average reimbursement amount, third party healthcare payors will define medical products and tests as investigational and experimental (CMS, 2018; FDA, 2019).

It is through these opinions and definitions that third-party payors formulate clinical policy bulletins (CPBs) to justify the reimbursement and coverage of non-investigational products and services used by healthcare providers. It is believed that clinical policies and payment denials can have a negative impact on the access of care by omitting services, technology, and FDA approved medical products defined as investigational that could otherwise benefit patient outcomes. This definition, although individualized and specific to each insurance

provider, may cause lack of access to diagnostic and curative care that could assist healthcare providers and improve patient outcomes.

The medical coding system originated in England during the 1600s, where it was used as a way of classifying deaths and estimating the cost through the statistical data collected from the London Bills of Mortality (Bocaccio, 1921). The causes of death were organized into the International List of Causes of Death, later adopted by the World Health Organization (WHO) to track international health developments and the mortality rate (Bacaccio, 1921). Through an international effort, the evolution of coding resulted in the adoption of the International Classification of Diseases-10 (ICD-10) diagnosis codes (Topaz, Shafran-Topaz, & Bowles, 2013). Common Procedural Technology (CPT) coding was developed in the United States in the 1960s by the American Medical Association (AMA, 2019). CPT coding was created as a way of documenting medical treatment through shorthand. These codes evolved and became endorsed by the federal government for universal use for the reimbursement of health insurance claims and are used today (CMS, 2018).

CPT codes were developed in 1966 by the AMA (2019) as a way to identify the services performed by doctors and other healthcare providers, and continue to be a daily necessity of the day-to-day functions of them. The original intent of CPT codes was not for use by third-party payers for reimbursement, but as a simplified means for healthcare providers to document the surgical procedures performed on their patients for the purpose of medical records. The first edition of CPT codes was two to four digits long, followed by the expanded second edition of CPT codes developed in 1970 with a five-digit format. Today, the CPT code identifies the services performed by doctors and other healthcare providers for reimbursement.

The Health Care Common Procedure Coding System (HCPCS) is a collection of codes that represent procedures, supplies, products and services which may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs (CMS, 2018). The CPT coding system is owned and maintained by the AMA and required for use in all Medicare billing (AMA, 2019). CPT codes are updated every year in October and are added, removed, and revised with each revision, as necessary. Changes in the CPT codes are governed by a 16-member editorial panel and can be initiated by providers, medical societies, and responsible organizations (AMA, 2019).

CPT codes are divided into three categories: Category I, which is used for reporting devices and drugs required for the performance of a service or procedure or assigned to procedures and tests within the scope of practice in the United States (AMA, 2019). These codes report services that are supported in medical literature, have received a 510 (k) clearance from the FDA, have an RVU assigned to the code, and are billable for reimbursement (AMA, 2019; FDA, 2019). Category II codes are tracking codes designed for measuring performance improvement, reducing the need for chart reviews (AMA, 2019). The codes provide necessary data for the Performance Measures Advisory Group (PMAG) and are not billable for reimbursement. Category III codes are temporary codes used for reporting emerging technology and are tracked with compiled data demonstrating use of emerging technologies before wide use and adoption (AMA, 2019). A Category III code must convert to a Category I within five years, or be renewed for another five years. Category III codes are billable, but not reimbursed, as the data are used to evaluate the RVU for the reimbursed amount (AMA, 2019; CMS, 2018).

With approximately 126 million beneficiaries of Medicare and Medicaid, or 16% of the U.S. population, Medicare and Medicaid set the gold standard of policy trends for third-party

payors, both for profit and not for profit; however, third-party payors set their own reimbursement policies and trends which varies from company to company, franchise to franchise, and state to state, as in the example of Blue Cross Blue Shield.

According to the research from CMS Physician Fee for Service Schedule, nasal function studies and the use of CPT 92512, specifically rhinometry and rhinomanometry, are technologies recognized and covered under Medicare and Medicaid (CMS, 2006, 2019). As early as 2000, the high-end, non-facility rate was $57.40, with a national average non-facility reimbursement rate of $60.24 in 2007, to a national average non-facility reimbursement rate of $60.55 in 2019 (see Table 1). The non-facility reimbursement rate is more common, as most nasal function studies are conducted in an office setting of a healthcare practitioner.

Table 1. Historical Reimbursement Rates for CPT 92512, Nasal Function Study

Year	Non-Facility Price	Facility Price
2019	$60.55	$28.83
2018	$60.48	$29.16
2017	$61.37	$29.07
2016	$61.58	$29.36
2015B	$62.18	$29.11
2015A	$61.86	$28.96
2014	$61.62	$29.02
2013	$62.94	$28.24
2012B	$61.95	$28.25
2012A	$61.95	$28.25
2011	$61.50	$28.88
2010B	$59.37	$28.76
2010A	$58.09	$28.14
2009	$57.35	$27.41
2008B	$59.80	$25.90
2008A	$59.80	$25.90
2007	$60.64	$26.15

Third-party payors reimburse specialists various contracted amounts through various methodologies, joining private insurance companies as a provider for their members. All

primary care providers (PCPs) and specialists agree to accept the insurance fee schedule and the payment and processing policies associated with the administration of these fee schedules. All fees paid by private insurance, together with the patient's copayment, deductible, and/or coinsurance (if applicable), are to be accepted as payment in full. Providers must not balance bill members for in-network covered services. If providers fail to precertify services, they may not balance bill the member.

Third-party payors formulate CPBs to justify the reimbursement and coverage of investigational and non-investigational FDA approved products and services used by healthcare providers by defining them as experimental and investigational, or not. Healthcare reimbursement is an element dictating how FDA approved medical technology and products will be used by the healthcare providers and the amount payable to the practitioner towards their revenue cycle (CMS, 2018; FDA, 2019).

Many medical innovations, tests, and products, such as instruments for nasal measurements, are a relevant part of clinical practice and should be considered as a standard of practice for reimbursement. Although medical products approved by the FDA are reimbursed by CMS with an RVU and a national average reimbursement amount, third-party healthcare payors, also known as insurance companies, tend to define medical products and tests as investigational and experimental (CMS, 2018; FDA, 2019). It is through these investigational and experimental definitions that third-party payors formulate CPBs to justify the reimbursement and coverage of non-investigational products and services used by healthcare providers. Clinical policies and payment denials have an impact on the access of care by omitting services, technology, and FDA approved medical products third-party payors define as investigational.

Characteristics of the third-party payor may play a role in determining the scope of covered benefits and reimbursement coverage of acoustic rhinometry (CPT 92512), by defining it as investigational and experimental, otherwise known as not medically necessary, in order to create the vexing notion of profitability. The scope of covered benefits is defined in the insurance contract, also called evidence of coverage or a summary of benefits. Documents will differ in the level of detail used to describe the covered benefits and services or circumstances in which services will be expressly excluded. Contract exclusion is any service not considered medically necessary by the payor. Section 1302 of the Patient Protection and Affordable Care Act (ACA) guides the Secretary of the Department of Health and Human Services (DHHS) by defining the essential health benefits (EHB) to include at least 10 categories of care to be equal in the scope of benefits provided by a typical employer plan through a benefit design.

From the practitioner and patient perspective, a significant issue has been that many determinations are vague and lack the accessible knowledge of decisions being overturned. Furthermore, these determinations may reflect a clinical policy the health insurer feels is most appropriate rather than taking into account the individual patient or healthcare provider recommendation. The benefit design of coverage sets out the parameters by which patients can obtain services.

A negative policy coverage determination may require a form of better understanding the technology and flow than to not use it outside of a central agency dictating national policy, and departing from the role of Medicare determination. Nonetheless, inconsistent coverage policy with well-documented, evidence-based medicine and years of market experience, with positive outcomes, reliability, specificity, and susceptibility, and that does not consider additional evidence to affect future coverage determination, has no value and may be deemed as unethical.

Ultimately, this creates a sense of social injustice in medicine of the haves versus the have nots in access to technology. The variations in access to healthcare technology show a call for a change to eliminate the consequences of the experimental and investigational label and improve healthcare policy.

Theoretical Framework

Content analysis is a tool used in research to determine the presence of certain criteria, concepts, or themes within the data. This study used a theoretical framework based on the components for the study to support the objective and explain a phenomenon of the results. By using a theoretical framework, the researcher was able to make inferences about different policies and factors associated with the experimental and investigational label around the text of the documents, and that the label should be eliminated due to inconsistencies in the healthcare insurer market and healthcare delivery.

As early as 2005, the term experimental and investigational became more commonly used among third-party payors as a way of limiting reimbursement and access to nasal function studies, hence, altering the way a healthcare provider can treat their patients and objectively measure outcomes from allergy provocation, to surgical procedures for sleep apnea, to improvements of chronic rhinosinusitis. The expectation and recommendation of third-party payors is to utilize subjective data and patient-directed self-assessment tools, such as the NOSE (Nasal Obstruction and Septoplasty Effectiveness Scale) or SNOT-20 (Sino-Nasal Outcome Test).

The impact on the quality of care could correlate to level of coverage and reimbursement for services. For example, research of CPT 92512, nasal function study, and coverage is limited, but the ICD-10 codes that correlate with the use of the CPT code could show the market use and

necessity of the code, regardless of the third-party payor policy. For example, there are approximately 675,000 sinonasal procedures performed each year, 300,000 of them sinus surgeries (Bhattacharyya, 2010). Of the 300,000 sinus cases, 60% are revision cases, meaning that surgery was necessary for a second time in order for the patient to have relief. Revision surgery rates following functional endoscopic sinus surgery (FESS) range between 7% and 50% and are influenced by many factors (Miglani, Divekar, Antoine, Rank, & Devyani, 2018). In a study of 29,934 patients, Smith et al. (2018) found the long-term revision rate to be 15.9%, with a mean time of 4.39 years and the short-term revision rate within one year of surgery at 12%. Each sinus procedure ranges in cost from $75 to $20,000, with a mean cost of $4,588. If the experimental and investigational label was omitted from coverage and reimbursement policies, the cost savings to the healthcare market could be marginal, yet the relief of not having to go through a second surgery could be priceless.

Gerhardt, Valiati, and Canto dos Santos (2018) looked into identifying factors that lead to a delay in the healthcare reimbursement process among Brazilian healthcare institutions. Gerhardt et al. concluded that although the healthcare reimbursement process is complex and vital to obtaining services from healthcare providers, there are process deficiencies circumventing operational patient care and operational services of institutions. These identifying factors, in addition to the experimental and investigational label, could potentially exacerbate the derogatory aspects of reimbursement and patient outcomes.

The experimental and investigational label is used more often in the pharmaceutical industry and is referenced in many documents from the third-party payor and the FDA. Such policies dictate the usage and compliance of usage under the experimental and investigational label among third-party payors and CMS (Aetna, 2019; CMS, 2018; FDA, 2019).

Purpose of the Study

The size of the third-party payor, the age of a CPB, the number of policy reviews, and the total number of resources validating the CPB may play a role in determining the scope of covered benefits and reimbursement coverage of medical devices and test such as acoustic rhinometry, CPT 92512, by defining it as investigational and experimental, or otherwise known as not medically necessary, in order to create the vexing notion of profitability.

The scope of covered benefits is defined in the insurance contract, also called evidence of coverage or a summary of benefits. The policies will differ in the level of detail used to describe the covered benefits and services or circumstances in which services will be expressly excluded. Contract exclusion is any service not considered medically necessary by the payor. Section 1302 of the Patient Protection and Affordable Care Act (2010) guides the secretary of DHHS by defining the EHB to include at least 10 categories of care to be equal in the scope of benefits provided by a typical employer plan through a benefit design

From the practitioner and patient perspective, a significant issue has been that many determinations are vague and lack the accessible knowledge of decisions being overturned. Furthermore, these determinations may reflect a clinical policy the health insurer feels is most appropriate, rather than taking into account the individual patient or healthcare provider recommendation. The benefit design of coverage sets out the parameters by which patients can obtain services.

The intent and purpose of the research builds on the efforts of change in healthcare policy and reimbursement to include the data and findings presented to third-party payors during annual meetings and congressional members in an effort to assist in changing this aspect of healthcare reimbursement policy. Furthermore, findings will support a consorted effort to eliminate the

label of experimental and investigational in clinical policies when referring to FDA approved products. This will contribute to a solution of consistent healthcare delivery as a result of consistent reimbursement policies.

The significance of the study was to understand the factors associated with the label of experimental and investigational and the potential healthcare cost implications for not covering the code based on accessable CMS data. Previous to 2005, all third-party payors paid for CPT 92512, but what happened to the interruption of reimbursement causing the experimental and investigational label to occur? From personal industry experience and a conversation with Ms. Karen Plude, the Director of Contracts and Insurance at SNAP Diagnostics in 2017, a dentist in the Northeast part of the country bundled the billing of a home sleep test, CPT 95806, and rhinometry, CPT 92512, otherwise known as nasal function study. During the reimbursement process, the third-party payor discovered the dentist submitting the incorrect code for the home sleep test, which was a 2-channel device. The 2-channel device was not covered under the third-party payor policy, which affected the coverage of rhinometry, then determined as also experimental and investigational; the 2-channel home sleep test device was legitimately experimental and investigable prior to the upgrade to a 3-channel device in 2009. Currently, the 3-channel home sleep test device is covered on nearly all plans. The third-party payor then implemented a CPB bundling the two devices as experimental and investigational, even though they are mutually exclusive and completely different. Furthermore, the label of experimental and investigational affected coverage of CPT 92512, as many heard of the coverage change from the leading insurer. The rebuttal was present with extensive clinical documents and statements of practice from professional organizations and letters of support from physicians. Post rebuttal, a minor change was initiated by separating the two devices on the same policy, but still call CPT

92512 as experimental and investigational; the debate continues. The findings of the research will present upon the request of Blue Cross Blue Shield National Association, as well as presented to Senator Ron Johnson (WI) for further review of healthcare policy and subsequent changes.

For this study, the resource dependence theory is applicable, as the external resources and clinical references affect the internal decision-making behavior of the organization. Resource dependence theory has implications that affect contract structure and many aspects of organizational strategy (Davis & Cobb, 2010). The argument of resource dependence theory is best summarized as resources being the basis of power, the organization's dependence on resources, power and resource dependence are directly linked, and thus power is relational, situational, and potentially mutual among departments and subsidiaries (Hillman, Withers, & Collins, 2009).

CHAPTER II

REVIEW OF THE LITERATURE

In a literature review of 22 million sources in a broad search from PubMed, Medline, ProQuest, and other knowledge surface and open access databases, no literature was found looking at the factors associated with the experimental and investigational label. The lack of research is related to many benefit policies differing from the definition or the exclusions under the member policy. The available literature from a key term search referenced reimbursement, coverage determinations, Medicare, Medicaid, and coding for billing purposes. Additionally, the subject of experimental and investigational labels and coverage of FDA approved products was not found in the literature review; therefore, the literature is under researched. Such a review of the experimental and investigational label is essential in order to determine that a controversial issue exists, one that defines the practical limits within clinical practice and patient care, and to obtain information about existing relevant literature and research that is preemptive of the reimbursement practice. This phase of the research provided the basis for the discussion that follows, particularly the segment concerning the reimbursement system, healthcare policy, and the review of relevant literature. In addition to explanations from the literature review, it provides a conceptual framework for the development of alternative reimbursement proposals and adjustments to healthcare policy.

The most common literature and research completed on the investigational label has been done by the FDA or those applying for 510(k) approvals, government enforcement agencies, and CPBs (FDA, 2019; GM Instruments, n.d.; Mendes, Wandalsen, & Sole, 2012).

This is a new, under-researched topic, with relatively little recognition and publication. The investigational label for FDA approved medical products and services by third party payors

has not been examined, but challenged and discussed within the medical industry through the practice of writing rebuttals for FDA approved medical products to be covered for reimbursement. A majority of the available literature and research on the experimental and investigational label targets pharmaceuticals or injectables and non-FDA approved devices and innovation. There are procedures that are labeled as not medically necessary, but not necessarily experimental and investigational.

Reimbursement and Coverage Determination

The layers of health coverage decision for reimbursement consist of three levels: covered benefit, coverage determination, and medical necessity (Garber, 2001). Covered benefits are a broad category of medical care covered as a mandate by deferral and state law. Coverage determination is a policy decision generally made by a third-party payor to a cover a particular health intervention for a particular enrollee population. The determination may be outlined by a particular set of clinical criteria that a patient needs to meet in order to receive the procedure or services. Outside of the determination, third-party payors may use the label of experimental and investigational. Dr. Alan Garber (2001:82) summarizes coverage by stating, "Coverage policy, in its broadest sense, is intended to promote value in a medical care by using reimbursement to favor the use of effective care and avoid payment for ineffective care."

When bringing a new device or technology to market in the United Sates, it is crucial to formulate a strategy for coverage after the long and complex path to commercialization post FDA approval (Clarke, 2017). It is extremely important to secure coding for coverage starting with Medicare, which is 20% of the national healthcare expenditure, and then the larger commercial payors, such as Aetna, UnitedHealthcare, Cigna, and BCBS, to name a few, as most providers will not carry the devices if reimbursement is unclear (Business Sweden, 2018; Clarke,

2017; CMS, 2018). Most commercial and public insurers follow suit of Medicare rulings for reimbursement and coverage when writing their policies.

Healthcare providers use medical coding to translate their services for reimbursement. Reimbursement (2003) by definition is compensation, repayment, or paying back. Third-party payor (2003) is defined as remuneration in exchange for goods or services. The two types of payment methods are the prospective payment paid to a healthcare provider at a predetermined rate for treatment, regardless of the cost of care for a specific individual patient, or the third-party payment, which is a contracted paid benefit to a provider or facility; the most common sources are private or governmental insurance (Rice & Unruh, 2016).

The understanding of who pays for services and how reimbursement dictates the market and use of the investigational and experimental labels is key to the success of the U.S. market (Business Sweden, 2018). In order for services and tests to qualify for reimbursing from insurance providers, a valid and applicable CPT code must be identified (Feldstein, 2015). In the case of CT 92512, the code is valid, with a national average reimbursement amount; however, to identify an applicable code does not guarantee that a third-party payor will provide payment for the service or test, as in the case of the larger insurers, such as Aetna (2002; CMS, 2018). By contrast, the largest healthcare insurer, UnitedHealthcare Group (2019a), does provide payment for CPT 92512, which will be reviewed later under methods. Furthermore, the third-party insurer may individualize their policy programs for coverage based on their interpretation of evidenced-based guidelines from nationally recognized sources and may be state and public policy specific (UnitedHealthcare Group, 2019b). Such language within the policy appears in Appendix C from UnitedHealthcare Group (2019c): the medical policy is standardized, yet

determined by the particular benefit plan. In a conflict of coverage determination, the benefit plan governs.

At the state and federal level, a statement of coverage may appear as no determination found, but a CMS (2019, para. 1) policy will state, "No returned records do not indicate coverage or non-coverage of a code or code set. Please contact your MAC for further information."

Third-Party Payor Process for Converage and Determination

Third-party payors (2003) are agents who work on behalf of parties such as patients and guarantee to cover any of their qualified healthcare payments either partially or in full to providers, also known as second parties, for coordinated care, products, testing, and services rendered. The insurers serve as intermediaries between the healthcare facility, or office, and physician for coordinated care, products, testing, and services, as such, have an influence on healthcare as it is today (Peabody, 2015).

Third-party payers may be defined as federal, state, or local government programs or private health insurance companies. Government programs include Medicare, which is age based, and Medicaid, which is income-based. Private third-party payors range in size and number of enrollees, but include the larger companies such as UnitedHealthcare Group, Wellpoint, Kaiser Foundation Group, Cigna, and Aetna.

Medicare

The basic criterion for making both national and local Medicare coverage decisions appears in the legislation that created the Medicare program. The legislation prohibits Medicare payment for services that are not reasonable and necessary for diagnosing or treating a medical condition. Federal statutes require the Medicare program cover services that are *reasonable and*

necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (CMS, 2013; Public Health and Welfare Act, 2013). In the public sector of third-party reimbursement and processes for coverage, all provider payments for services must be based on the reasonable cost of services covered under Title XVIII of the Social Security Act and must be related to the care of the beneficiaries, or the case of acute care hospitals, the perspective payment process system (Hoffman, 2009). CMS has included all necessary and proper costs incurred and rendering the services, subject to principles relating to specific items of revenue cost. The reasonable cost approach is utilized for Medicare (Perry, 1977). In the provider reimbursement manual, Part One, Chapter 21, of the CMS (2015) guidelines, the definition of reasonable cost in section 2102.1 is:

> Reasonable costs of any services are determined in accordance with regulations establishing the method or methods to be used, and the items to be included. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs. The objective is that under the methods of determining costs, the costs for individuals covered by the program are not borne by others not so covered and the costs for individuals not so covered are not borne by the program. (para. 1)

Constant with the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize their costs and that its actual costs do not exceed what a prudent and cost-conscious patient pays for a given item or service. If costs are determined to exceed the level that such patient incurs, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program (CMS, 2006).

CMS has developed the fee schedules based on new proposals, including those with coding and payment changes, as recommended by the CPT editorial panel and a a Medicare Advocacy Recovery Coalition (MARUC) office. Each Medicare administrative contractor (MAC) determines the average reimbursement rate for CPT 92512, as shown in Table 2. It will vary from area to area in the country based on the zip code (CMS, 2019).

Table 2. MAC Physician Fee Schedule for CPT 92512, Nasal Function Study (CMS, 2019)

MAC Locality	Non-Facility Price	Facility Price
310200	$59.17	$28.37
710213	$54.91	$27.25
111254	$63.30	$29.24
111255	$63.22	$29.16
118271	$63.23	$29.17
111256	$63.22	$29.16
111257	$63.24	$29.18
118218	$67.97	$30.64
118226	$67.97	$30.64
111258	$63.22	$29.16
111259	$63.22	$29.16
111260	$63.22	$29.16
111251	$70.91	$31.08
118217	$67.46	$30.17
111261	$63.22	$29.16
111262	$63.51	$29.45
111263	$64.06	$29.43
111264	$64.40	$29.48
118272	$64.94	$29.55
111207	$73.96	$31.94
111252	$72.48	$31.54

Medicare recognizes the cost could be different from institution to institution or from provider to provider, but it also states where a particular institution or provider's cost is found to be substantially out of line with another institution or provider in the same area of the same size and scope (CMS, 2006, 2018; Perry, 1977). Costs are fit into fee schedules, which are a comprehensive listing of the maximum and minimum values used to reimburse a facility and/or

other providers on a fee-for-service basis for each MAC (CMS, 2006). A MAC is a private healthcare insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or durable medical equipment (DME) claims for Medicare fee-for-service beneficiaries. Medicare has a detailed process and standards for making coverage determinations and does not use the label of experimental and investigational on FDA approved devices; however; the Medicare coverage determination process is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury and within the scope of a Medicare benefit category (CMS, 2018). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation (CMS, 2011; Foote & Town, 2007). In some cases, CMS's own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD; CMS, 2013).

Medicaid

Unlike Medicare, which is age- and disability-based, Medicaid is income- and needs-based, covering low-income adults, children, pregnant women, elderly adults, and people with disabilities. Medicaid is administered by states according to federal requirements, is funded jointly by the state and federal government, and is rapidly becoming the largest purchaser of healthcare services in the United States (CMS, 2018; Manatt Health Solutions, 2015).

Under Title XIX of the Social Security Act, federal funds are matched to the states for Medicaid program funding, with the stipulation of each state deciding eligibly, types and range of services, payment levels, and operating and administrative procedures (CMS, 2018; Public

Health and Welfare Act, 2013). Under federal law, Medicaid law grants a significant portion of coverage determination to the states within the mandates of care categories. Federal rules stipulate the coverage policies, to include a broad range of benefits, but leave the definition of qualified covered services up to each state. This also includes commercial payor backed Medicaid and Medicare Advantage programs, such as Fallon and Anthem (Livingston, 2019).

Historically, state insurance determinations are without formal written policies and made informally, with reviews often imitated by medical company vendors, providers, or consumers. Few states have a systematic process for reviewing evidence and coverage for new technologies, and few systemically review past coverage determinations for reviews of updated polices or for outdated, less effective services (Manatt Health Solutions, 2015).

Upon extensive research for Medicaid literature coverage and the use of the experimental and investigational label, there were no findings for use as a means for non-coverage in most states; however, that is not to say that there areare not policies that recognize the label of experimental and investigational, as in the case of drugs. One policy example would state such criteria as not covering the procedure, product, or service related to this policy when

> The beneficiary does not meet the eligibility requirements, the beneficiary does not meet the criteria listed in the policy, or the procedure, product, or service duplicates another provider's procedure, product, or service, or the procedure, product, or service is experimental, investigational, or part of a clinical trial (North Carolina Division of Medical Assistance, 2015, para 3).

Commercial Payors

While federal and state laws and regulatory bodies require third-party payors to maintain a high degree of complete discretion of coverage determinations, the literature review shows

many individual commercial payors determine and define what is a medical necessity and experimental and investigational for reimbursement (Manatt Health Solutions, 2015). Typically, commercial payors publically provide particular coverage determination policies and processes on their websites, specifically when coverage is labeled experimental and investigational or not medically necessary; unless posted, the device and technology is actionable and covered for reimbursement, as in the case of UnitedHealthcare (Aetna, 2019; UnitedHealthcare Group, 2019a). For example, UnitedHealthcare Group (2019c) posts their medical policies and medical benefit drug policies online and express their determination of coverage for health service (e.g., test, drug, device, or procedure), so long as it is proven and effective based on the published clinical evidence. They are also used to decide whether a particular health service is medically necessary or experimental and investigational. Services determined to be experimental, investigational, unproven, or not medically necessary by the clinical evidence are typically not covered; however, clinical rebuttals from the healthcare provider deeming medically necessity may be submitted, as well as medical device industry requests for consideration of coverage upon the date of the policy review (GM Instruments, 2019; Weber, 2008). The difficulty of this type of reimbursement policy lies in the discretion of the third-party payor and their coverage determination as completely subjective and potentially damaging to patient care, outcomes, financial resources, and the patient-physician relationship, which will be discussed as part of the research (Dorr-Goold & Lipkin, 1999; Foote & Town, 2007).

By definition, coverage determination guidelines are used to determine whether a service falls within a benefit category or is excluded from coverage and may address such matters as whether services are skilled versus custodial or reconstructive versus cosmetic (Aetna, 2019; BCBS National Association, 2018; UnitedHealthcare Group, 2019b). Benefit coverage for

health services is determined by the member specific benefit plan document, such as a Certificate of Coverage, Schedule of Benefits, or Summary Plan Description, and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations, hence described as medically necessary or experimental and investigational (Aetna, 2019; BCBS National Association, 2018). In the event of a conflict, the member specific benefit plan document supersedes the policies and guidelines, the practitioner, and medical device company representative (BCBS National Association, 2018).

Medical policies, medical benefit drug policies, and coverage determination guidelines represent a portion of the resources used to support coverage decision making and are developed as needed, are regularly reviewed and updated, and are subject to change upon the discretion of the insurer; however, there is a rebuttal process leading up to and including a state complaint (BCBS, 2019; UnitedHealthcare Group, 2019b). Additionally, the information presented in these policies and guidelines is believed to be accurate and current as of the date of publication, and is provided on an *as is* basis. UnitedHealthcare Group (2019b) may use tools developed by third parties, such as the Milliman Care Guidelines, to assist in administering health benefits. The Milliman Care Guidelines are non-published, proprietary, and intended to be used in connection with the independent professional medical judgment of a qualified healthcare provider and do not constitute the practice of medicine or medical advice with variances in state policy (UnitedHealthcare Group, 2019b). Commercial insurers' medical policies, medical benefit drug policies, and coverage determination guidelines do not include notations regarding prior authorization requirements or view the services that are subject to a notification/prior authorization requirement.

As it relates to the coverage of FDA approved products and the label of experimental and investigational, BCBS Association, a national federation of 36 independent, community-based, and locally-operated BCBS National Association (2018, para. 1) companies, states on their website:

> Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement. We develop Medical Policies to guide Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, and explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

While private payors do not have to follow the rules set forth by the federal government and CMS, many find the CPT coding system for coverage and reimbursement as a well-established and familiar system (Beck & Margolin, 2007). Private payors bound to non-capitated contracts will often set reimbursement rates based on a percentage of the Medicare fee schedule and regional location of the physician and facility, as documented in Table 2. Beck and Margolin (2007) also found that the larger payors, such as Aetna and UnitedHealthcare Group, have taken this one step further by using Medicare payment guidelines to develop their fee schedule and will adjust the payment amount based on the individual service provided.

Clinical Measurement Metrics for Coverage Determination

Measurement, as a rule, is a critical tool to monitor progress and outcomes while driving improvements in patient care, technique, and outcomes (Saver et al., 2015). Increasingly, metrics collected for quality improvement purposes are included in reimbursement methodologies for hospitals and clinicians in pay-for-performance frameworks. Without the meaningful coordination of care, effective measurement activities become limited and further obstruct the positive trends of healthcare or an organization, yet an overabundance of metrics can become burdensome (Dunlap et al., 2016). Over the next few years, clinical metrics for coverage determination will be driven by physician specialty societies to determine best practices, cost-effectiveness, treatment outcomes, and practice variations with associated costs (Dunlap et al., 2016). It is from these clinical measurement metrics that evidence-based medicine and policy are derived and become the basis for the clinical policy bulletins.

Many payors apply evidence-based medicine approaches to their coverage decisions as a foundation for systematic reviews of data on the effectiveness of device and treatment technologies. When new technologies are adopted by the public payor sources, such as Medicare and Medicaid, the Medicare Coverage Advisory Committee holds public meetings in front of a board of various members from industry, co-chairs from six evaluation panels. First, the panel determines whether the scientific evidence is sufficient to draw a conclusion of efficacy in routine clinical use (Garber, 2001). The second step is for the panel to determine the benefit of the technology (Garber, 2001). If the evidence is adequate, the panel determines whether the treatment device or technology is less effective, more effective, or as equally effective as compart to the standard medical protocol (Aetna, 2019; Garber, 2001). Beyond these panel

reviews, little outside input is considered for a coverage determination or consistent for coverage with adequate evidence. The Medicare rules and metrics determinations are complex.

Commercial payors have varied approaches to evidence-based medicine and coverage determinations directed by a technology evaluation center (TEC) to determine whether the technologies improve patient health outcomes (BCBS National Association, 2018). Once the clinical metrics and data are reviewed by the TEC, the Medical Advisory Panel (MAP) ratifies the review and distributes the reports to the provider groups and healthcare plans for reimbursement determination (BCBS National Association, 2018).

Garber (2001) summarizes coverage processes and policies using evidence-based medicine as unclear on how coverage policy affects healthcare spending. Garber further notes that evidence-based processes become overwhelming for new technologies by requiring efficacy studies and slowing the process. By slowing the evidence-based policy process down, it does not necessarily lower any cost of healthcare plans. Product used in place of new technology, as in this case of subjective measurements such as the SNOT- 22 over subjective measurements from acoustic rhinometry, can collect evidence of becoming more costly in treatment plans due to surgical revisions, as an example (Garber, 2001). Also, the speed of adopting new technologies, the use of medical services, and the quality and outcomes of patient care provided by third-party payor members can be affected by the coverage policy because of the varying amounts of time for the review of the evidence for writing coverage policies (Garber, 2001). The caveat is if evidence-based coverage policies can cope with the rapidly changing technology and innovation as we know it today, specifically for particular patient populations where innovation and interventions can work for them. On the contrary, Garber (2001) notes that third-party payors create a moral spending hazard of overuse, since enrollees and members do not know the cost of

care nor are the full cost of services consumed by them a complete financial liability. The cost containment of evidence-based clinical policy coverage policies is not the most important reason to create coverage policies, but to promote effective care. Evidence-based coverage policy also sends a message about which innovations are considered effective, which could be seen as a form of bias or validation to interventions that may not be subject to regulatory review.

Medicare (2016) and the FDA (2019) use metrics and evidence-based information to help develop compliance and inspection policies and practices, such as risk-based inspection scheduling of drug and device manufacturers, to improve the FDA's ability to predict and possibly mitigate future adversarial events and to encourage the medical device industry to implement state-of-the-art, innovative quality management systems for manufacturing (U. S. Food and Drug Administration, 2019). Compliance tracking and reporting for the FDA, Code of Federal Regulations (CFR), and International Standards Organization (ISO) 9001 standards often require companies to use several different systems. Manufacturers rely on supply chains to meet stringent product quality and compliance standards; supplier quality management and compliance in medical device manufacturing is a prerequisite for a coverage determination (FDA, 2019). Saver et al. (2015) best summarized clinical metrics for a coverage determination, "Evidence connecting many quality measures with improved health outcomes is modest, and metrics may be chosen because they are easy to measure rather than because they are evidence-based" (p. 1).

Coding for Billable Reimbursement

Understanding physician reimbursement and the limitations to the experimental and investigational label for reimbursement is critically important to patient care and the sustained revenue health of any physician practice (Beck & Margolin, 2007; Blount, Waters, & Gold,

2001). Reimbursement involves more than the predetermined amount and contract guidelines, it is a long, and often convoluted, process that starts when a patient first contacts the physician (Beck & Margolin, 2007). After contacting the physician's office, the patient visit is completed and then coded for payment. To appropriately maximize reimbursement, the healthcare provider must know the basics, such as the correct coding, the business of medicine, the basic rules of Medicare, billing guidelines, and the private payors varying reimbursement rates and policies, which are tied in some form to the Medicare system (AMA, 2019; Beck & Margolin, 2007; Blount et al., 2001; CMS, 2019).

In 2015, a change from the International Classification of Diseases, ninth revision, (ICD-9) to the International Classification of Diseases, 10th revision (ICD-10), became a disruptive challenge for the medical coding and billing personnel and healthcare providers, as the two coding systems are different in their diagnosis and procedural codes. With the many codes already available, additional codes allowed a more specific and detailed recording of work and plan of care during the transition process, yet the label of experimental and investigational remains (Stauffer, 2012). The coding system has been important as it moves to improve patient care in the U. S. healthcare industry during the coding and billing reforms and transitions; hence, the ICD-10 came with an increase in the number of codes that allow for higher levels of specificity in reimbursement and coded patient data (Hohlbein, 2015). The increase in codes is determined to allow reimbursement and clinical documentation to be more specific and for healthcare providers to achieve accurate coding for better reimbursement and practice revenue, yet, as previously mentioned, the experimental and investigational label for FDA approved products and technologies remains in the verbiage of coverage policies from commercial third-party payors. The ICD initiative, with concurrent documentation review, will help the healthcare

providers to verify that the clinical status of their patient has been accurately captured, resulting in more precise reimbursement prior authorizations, appeals, and rebuttals for denied claims (Hohlbein, 2015). The accurate reporting of the medical diagnoses is essential in providing quality, modern healthcare with objective measurable outcomes. Conclusively, the ICD-10 codes are the foundation of medical billing and coding and are essential during the reporting processes for the uninterrupted care of patients; as medical terminology and new technology and medical advancements are approved, medical billing and coding will change. The way healthcare professionals provide treatment depends upon continued research and reporting. In essence, new research and healthcare innovation mean new codes and procedures, including those labeled as experimental and investigational.

CPT 92512 was created and approved as a billable code in the 1980s as part of the Omnibus Budget Reconciliation Act of 1987 when CMS implemented the use of CPT codes for outpatient hospital procedures. In 1996, and as part of the Health Insurance Portability and Accountability Act (HIPPA), the Department of Health and Human Services designated CPT as the language and standard for electronic healthcare transmission for the payment of services. The CPT coding system is the universal billing language of public and commercial payors for services rendered by healthcare professionals and facilities. In the event a company wants to bring the request of a new code for reimbursement, and avoid the label of experimental and investigational, a seven-step process for developing a new code is available by submitting revenues to the AMA CPT Editorial Panel, beginning with a Type 3 code, as previously discussed (AMA, 2019).

Clinical Policy Bulletins

Clinical policy bulletins (CPBs), which differ from clinical practice guidelines, describe the status of medical technology at the time of development and statement of benefits for coverage, are compliant with all applicable laws and regulations, and the standard of accreditation and regulatory agencies and the CMS (AmeriHealth HMO, 2019). Clinical practice guidelines are not a statement of benefits, but a roadmap or resource to enhance patient outcomes and support clinical practice consistent with a national standard of care from recognized healthcare organizations or specialty organizations, such as the American Academy of Otolaryngology-Head and Neck Society (AAO-HNS). Clinical practice guidelines are accepted and considered as an absolute minimum standard of care, yet individualized for clinical decisions specific to patient medical needs. This aspect of the policy is important when determining coverage and reimbursement as experimental and investigational while defending the elimination of it as a matter of universal healthcare policy.

The foundation of CPBs is referenced citations of peer-reviewed published medical journals, reviews of available studies on a particular topic, evidence-based consensus statements, expert opinions of healthcare professionals, and guidelines from nationally recognized healthcare organizations. Most clinical or medical policies follow suit of the CMS with national reimbursement rates that ultimately direct clinical policy, healthcare provider acceptance, and clinical use of FDA approved medical products and services. Clinical policies can harm the access of care by omitting services, technology, and FDA approved medical products defined as investigational that could otherwise benefit patient outcomes.

For Aetna (2019), the CPB is used to determine medical coverage by way of detailing the services of procedures they consider medically necessary, cosmetic, or experimental and

unproven. The CPB helps Aetna decide what they will or will not cover and is based on peer-reviewed, published medical journals; a review of available studies on a particular topic; evidence-based consensus statements; expert opinions from healthcare professionals; and guidelines from nationally recognized healthcare organizations (Aetna, 2019). There is a different policy for Pennsylvania Medicaid, which could be true with most insurers (Aetna, 2019). Most CPB changes are not effective until 30 days after the last review date. The historical section of the CPB is located on the policy page and shows the policy updates, revisions, additions, and deletions, which are available publicly on the website and sorted by date, then topic. The policy changes include commercial coverage, as well as Medicare coverage.

Upon further review of the literature and the Aetna website, an interesting observation related to the pre-certification section under the provider section of the website is that when CPT 92512 is entered in the search, the policy states,

> The procedure code entered was not found on the Aetna participating provider medical recertification list. If you're a participating provider, no precertification is required when this service is performed as an outpatient procedure for a medical or surgical diagnosis. This procedure code may require pre-certification for behavioral health diagnoses. (Aetna, 2019, para. 1).

This is very contrary to the experimental and investigational label when entering *rhinometry* in the Aetna (2019) website CPB search engine. Within the medical clinical positions and limitations, it states the list of services and supplies that are not generally covered or are considered experimental and investigational procedures, except for coverage for medically necessary routine patient care costs for members participating in a clinical trial concerning the

treatment of cancer and other life-threatening diseases or conditions (Aetna, 2019). The verbiage for CPBs seems clear yet vague, because within this particular example, it is stating experimental and investigational procedures are necessary within the scope of the clinical trial, yet are outside coverage determinations from the definition of medically necessary to patient care. So, in essence, a healthcare provider could legitimately use CPT 92512, yet go through the dispute process for a reconsideration or appeal of a denied claim. The ambiguity of the policy leaves the payor dictating providers' clinical practice, yet leaving them with time-consuming appeals and a potential financial loss. Due to these policy inconsistencies, Bogardus, Geist, and Bradley (2004) examined the use of deceptive interactions of healthcare providers with third-party payors to care for their patients the way they see fit, not an insurer, further contributing to the fraud healthcare financial system.

Regulatory Consideration for the Experimental and Investigational Label

The FDA is the formal regulatory body that defines experimental and investigational and is the precedent for a coverage determination by third-party payors. The FDA defines investigational is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device (FDA, 2019). Investigational is defined as services or supplies that cannot be marketed lawfully without the approval of the FDA; are the subject of the ongoing phase I, II, or III clinical trials; and reliable evidence shows that the consensus among qualified objective experts regarding the inherent nature of the medical device is that further basic science research, laboratory-based clinical studies, clinical studies, clinical outcome research, or clinical trials are necessary to determine their safety, efficacy, and anticipated outcomes, as compared with the standard means of treatment or diagnosis of the condition in question. As part of the investigational medical product category, sub-categorical variables exist

within the definition: Reliable evidence includes, but not limited to, published studies in objective authoritative medical and scientific peer-reviewed literature of adequate well-control clinical trials with their written protocol(s) and informed consent(s) which were used by the treating facility or substantiated by another faculty investigating the same medical device. Medically necessary is defined as a fully approved device that appears to be safe, may be effective, and therefore are the most appropriate treatment for immediate life-threatening or serious disease or illness which has no satisfactory alternative treatment (FDA, 2019). The devices are approved by the FDA commissioner, and off-label use which is a legally marketed product for a purpose other than that approved by the FDA, but in doing so, must be well informed about the product, must base its use on formed scientific rationale and sound medical evidence, and must maintain records of the products use and effects (Blair-Holbein, 2009; FDA, 2019).

An investigational device is a device, including a transitional device, that is the object of an investigation (Blair-Holbein, 2009). Investigational device exemption (IDE) refers to the regulations under 21 CFR 812 (Labeling of Investigational Devices, 2007). An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and met all the requirements under 21 CFR 812. The FDA (2019) defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a part or accessory that is: Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended

purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Under CMS guidelines, the experimental and investigational label *does not* appear to have a regulatory effect, as coverage is defined that "all devices that may be covered under Medicare include the following categories" (CMS, 2015, para. 3): a) Devices approved by the FDA through the Pre-Market Approval (PMA) process; b) Devices cleared by the FDA through the 510(k) process; c) FDA-approved Investigational Device Exemption (IDE) Category B devices; and d) Hospital IRB-approved non-significant risk devices.

As previously discussed in the literature review regarding commercial third-party payors, they can make self-determination, regulatory coverage policies as it related to the explanation of the experimental and investigational label. Aetna (2002, para 1, 2019) defines experimental and investigational with specific criteria as it relates to diagnosis and treatment. Throughout the policy, Appendix D lists the criteria specific to coverage; a current diagnosis that will most likely cause death within one year or less despite therapy with currently accepted treatment; when standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and the proposed treatment is likely to be beneficial to the member based on at least two documents of medical and scientific evidence; and, the member is to be treated as part of a clinical trial. The clinical trial criteria for coverage are satisfying of the following criteria listed in Appendix D. Aetna (2002) defines acceptable peer-reviewed literature, biomedical compendia, and other medical literature as resources that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR). Medical and scientific evidence is defined

as peer-reviewed scientific studies published in or accepted for publication by medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x) that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

BCBS' (2019) considerations for the experimental and investigational label state the following guidelines for investigational and experimental procedures policy from their website:

> You are not covered for a service, supply, device, or drug deemed investigational or experimental. A treatment is considered investigational or experimental when it has progressed to a limited human application but has not achieved recognition as being proven effective in clinical medicine. To determine investigational or experimental status, we may refer to the technical criteria established by the Blue Cross and Blue Shield Association, including whether a service, supply, device, or drug meets these criteria. (para. 1)

BCBS National Association (2018) has final approval from the appropriate governmental regulatory bodies and how they utilize coverage criteria. These criteria are considered by the BCBS Association's MAP for consideration by all BCBS member organizations. While we may rely on these criteria, the final decision remains at the discretion of our medical director, whose decision may include a reference to, but is not controlled by, policies or decisions of other BCBS member organizations. Scientific evidence, by definition, must permit conclusions concerning its effect on health outcomes, the improvement of the net health outcome, is beneficial as any established alternatives, and the health improvement is attainable outside the investigational setting.

The aforementioned experimental and investigational regulatory policies from commercial payors appear contradictory to federal regulatory policy defining the label, resulting in non-coverage.

Experimental and Investigational Label Concepts and Theories of Non-Coverage

One challenging aspect of third-party payor coverage decisions is their definition and supportive documentation for the experimental and investigational label, resulting in limited access to innovative technology and devices, potentially improved patient outcomes, and quality of life from the lack of necessary revision surgeries. The coverage policies continue to be subjective based on the views of individual medical directors and fail to consider the financial burdens of the contradictory labels, aside of the federal regulatory and approval agencies.

Third-party payors may classify a company's technology or medical product as experimental and investigational if the company has not demonstrated otherwise with FDA approval data for the products. Even with adequate approval data and clinical evidence, a payor may classify the product as investigational, deny coverage, and not recognize the approved CPT code as assigned by CMS, which could ultimately affect access to healthcare providers and patient outcomes. To reverse the negative coverage decisions, a rebuttal strategy and standardization process is needed; however, the validity lies within the interpretation and understanding of the reviewing body. Within the limitations of access and review board understanding, the negative impact of using the investigational label on FDA approved medical products will continue to have an impact on the healthcare system as a whole.

The process model of commercial payors' coverage polices for CPT 92512 as experimental and investigational is best described as a continuum listed in Figure 1. It is through these investigation and experimental definitions that third-party payors formulate justification of

the reimbursement and coverage of non-investigational products, FDA approved services used by healthcare providers. Clinical policies and payment denials have an impact on the access of care by omitting services, technology, and FDA approved medical products third-party payors define as investigational. The investigational and experimental definition, although individualized and specific to each third-party payor, may cause a lack of access to diagnostic and curative care that can assist healthcare providers and improve patient outcomes. Figure 1 displays the 3-tiered process of coverage: request, review, and policy implementation.

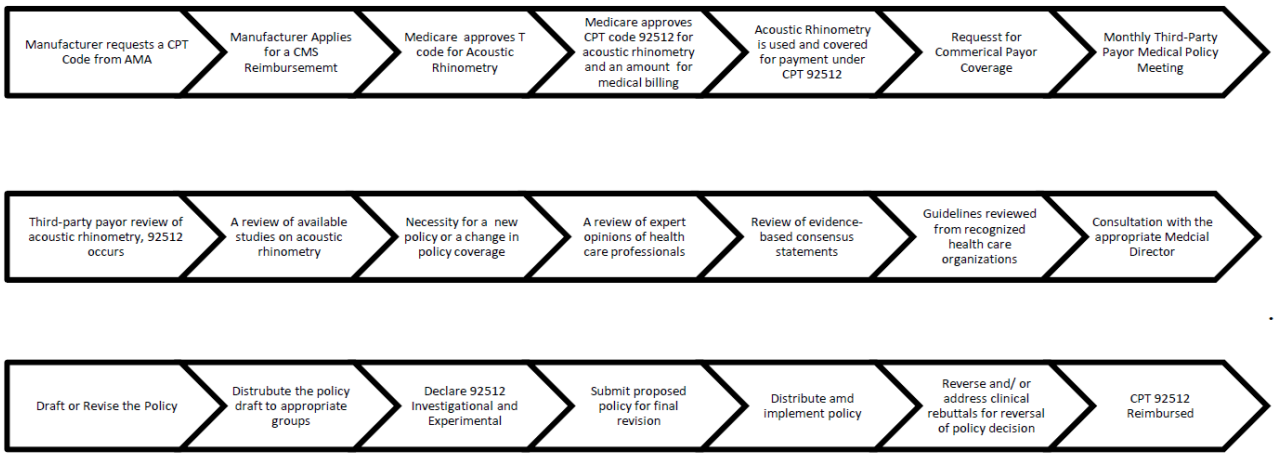

Figure 1. Process Model of Third-Party Payor Clinical Policy Bulletin and Reimbursement Determination of CPT 92512

Beyond the payor reference, there is an impact on the systems that should be considered and they affect the experimental and investigational label has on a particular population. As early as 2005, the term experimental and investigational became more commonly used among third-party payors as a way of denying reimbursement and access to nasal function studies, hence, altering the way a healthcare provider can treat their patients and objectively measure outcomes from allergy provocation to surgical procedures for sleep apnea to improvements of chronic rhinosinusitis. The expectation and recommendation of third-party payors is to utilize

subjective data and patient-directed self-assessment tools, such as the NOSE (Nasal Obstruction and Septoplasty Effectiveness Scale) or SNOT-20 questionnaires to correlate results with patient satisfaction (American Academy of Sleep, 2019; Wallace, Dykewicz, Bernstein, et al.,2008).

If we look at the fundamental system to a complex health issue, the characteristics remain the same. For example, the label of experimental and investigational removes the concept from a singular level to a whole level, but the characteristics remain the same (insurance coverage). If we can create a preventative environment through clinical assessment that is supported by third-party payors, then healthcare providers can provide preventive care, reduce costs by minimizing the need for revision surgeries, and maintain a quality of life for their patients without enduring additional surgical pain.

It is this premise that the most probable and common system thinking theories are unintended consequences that occur when the outcome of a decision has a negative impact, such as revision surgery and/or injustice or inequality to healthcare access and better health on the patient population (lack of reimbursement), rather than the intended positive outcome of improving patient outcomes with quantitative and qualitative data (reimbursement for objective measurements; Steinberg, Tunis, & Shapiro, 1995). The other theory is the equifinality where the reimbursement system is unified at the organizational land national levels with a universal healthcare policy for coverage and the elimination of the label of experimental and investigational, albeit each third-party payor will have a varied policy (Johnson, & Anderson, 2017; Johnson, Anderson, & Rossow, 2020).

The evidence of common systems characteristics of the experimental and investigational label and the reimbursement programs of third-party payors within the theoretical systems thinking examples include, but are not limited to, six key themes (Anderson & Johnson, 1997).

The first is interconnectedness, which is necessary for a shift in mindset from a linear feedback loop to a circular loop, as in Figure 1. Here everything is reliant on one event preceding another in order to untangle the system of inconsistent reimbursement and CPBs among third-party payors. Synthesis refers to the combination of two or more events to create something new while understanding the whole beyond the parts of the system at the same time is additional to the relationship connectedness that comprises the whole. As in the example of the experimental and investigational label, clinical reviews, provider support, and professional society opinions are the parts associated with the whole, but combined can create a reversal in the decision not to cover CPT 92512. From a system of parts, we know that larger things become through emergence. Emergence describes the universal approach from individual items and is the outcome of synergistic function the individual silos or parts interacting together. For example, when the communication and clinical facts are present, the clinical policy bulleting and decision did not cover a procedure that comes together.

Feedback loops are the fourth theme, with characteristics that support the flows between the elements of the system. Two types of feedback loops are reinforcing and balancing; reinforcing is negative in tone, as in the example of behavior over time in Figure 2, and balancing is positive, defining equilibrium within the system. In the case of the experimental and investigational label, reinforcement creates chaos in the office of the provider by not knowing what third-party payors will cover, but could be balanced with the elimination of the label experimental and investigational. To gain perspective of the feedback loop, we need to look at causality, or how one part results in another in an evolving system. Causality in systems thinking is about the way parts of the whole influence one another, and in this case, it is the

practice healthcare provider and operations of an organization influenced by the third-party payor based on their reimbursement policies (Figure 2).

Lastly, systems mapping is the last characteristic and principle to identify and map the elements of things within a system to better understand how they interconnect, act in a complex system, and relate within the system. These types of insights from mapping can be used in a causal loop diagram to understand and to develop policy decisions for the most effective working system. Figure 2 illustrates the causality of the third-party payor and the delivery care choices by a healthcare provider and the interrelation of treatment choices for better patient outcomes and reimbursement. Figure 3 illustrates the behavior over time of non-coverage of CPT 92512.

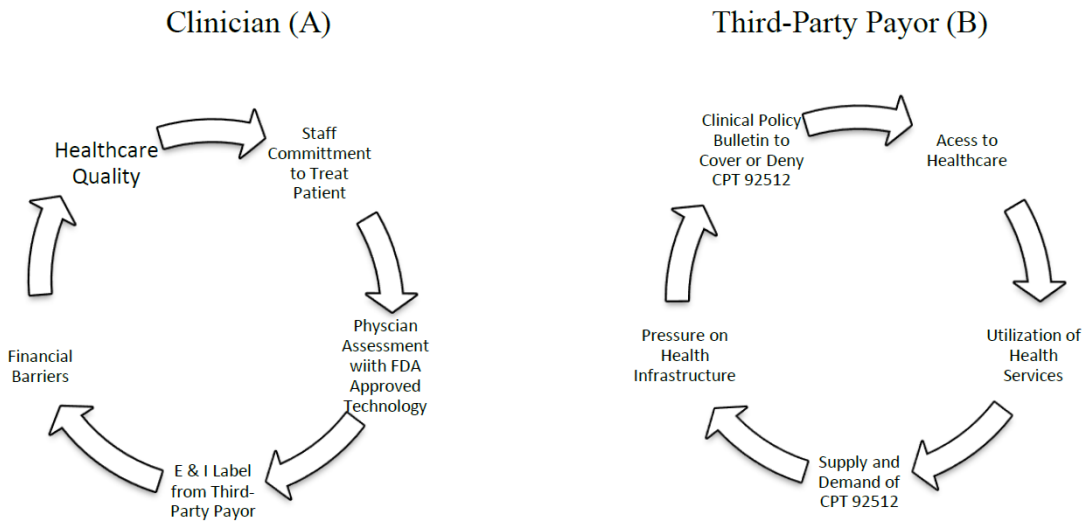

Figure 2. Causal Loop Diagram of A and B

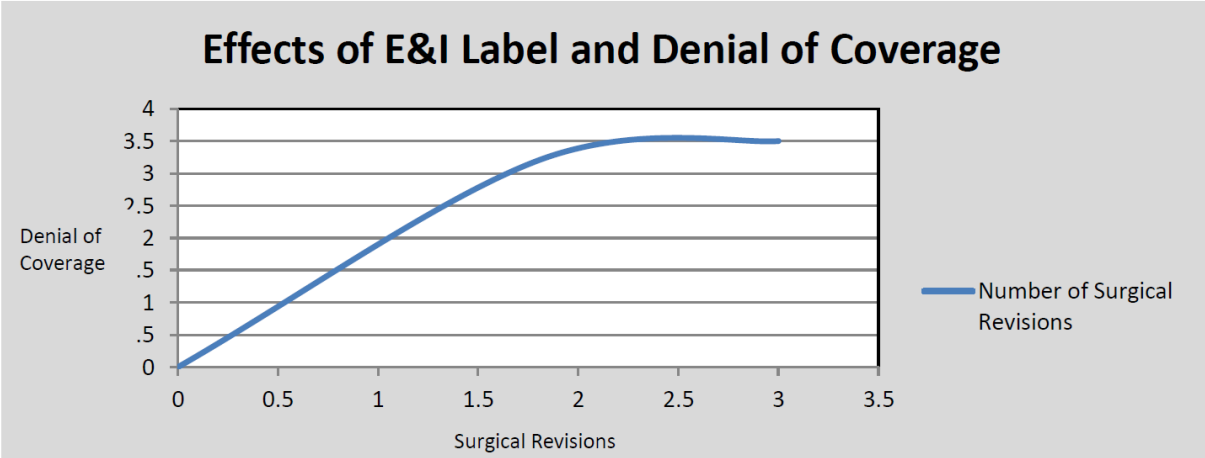

Figure 3. Behavior Over Time

The experimental and investigational label used by third-party payors is reinforced by the denial of coverage for CPT 92512, nasal function study/objective nasal measurements, and encourages the lack of usage and the lack of thinking outside the box using technology for more objective and quantifiable data measuring patient outcomes (GM Instruments, 2019). There is pressure among some insurance companies to maintain costs and save money, but denying claims for technology that could assist in better patient outcomes by way of objective, qualitative measurements is contradictory and dictates to a healthcare provider how to practice healthcare delivery.

Within the literature review, it is advisable for any medical device company to develop quick strategic actions by compiling a comprehensive body of evidence to reverse any negative coverage decisions where the medical technology is classified as experimental and investigational (Gregory, 2017). The most effective plan is to present data and justification requesting a review by producing and presenting published studies or clinical outcomes, economic analyses demonstrating potential savings or even budget neutrality, support of the

technology or device by medical specialty societies within their treatment guidelines, or support by way of direct communications from physicians requesting the technology (Gregory, 2017). It should be noted that in the example of BCBS National Association (2019), the policies of Blue Shield National Association and the AMA (2019) recognize CPT 92512; however, some of the subsidiaries do not based on the lack of usage of the code, hence calling it experimental investigation and justifying the loophole for non-coverage.

So, the argument remains that if commercial, private payors often follow Medicare reimbursement policies using Medicare's fee schedule as a starting point for setting payments and often creating similar coverage policies, why then would the commercial payor use the label of experimental and investigational (Deverka & Dreyfus, 2014)? Furthermore, private payors continue to conduct technology assessments from various sources, some legitimate and apropos and some not, before providing coverage and reimbursement for new technology (Deverka & Dreyfus, 2014). The recommendations on how to facilitate more of systems thinking approach and to assure effectiveness and sustainability in coverage policy are by eliminating the label of experimental and investigational. Furthermore, by identifying the variables associated with the label of experimental and investigational that reflect the original problem of non-coverage by third-party payors, the policy would change at a national and organizational level among all health insurance companies and would follow suit of Medicare and Medicaid reimbursement policy.

Potential Healthcare Financial Aspects of the Experimental and Investigational Label

The literature review for potential implications of using the experimental and investigational label focuses more on pharmaceuticals and less on devices, but could be a consideration for both.

Most commercial third-party payors exclude coverage for defined experimental and investigational technologies, but fail to define what the standards are for the use of exclusionary provisions that limit their financial liability, keep the cost of insurance down, and encourage more subjective treatments or assessments be used by eliminating innovative technology and devices (Harness, 1996). This unclear exclusionary provision could often result in litigation towards the provider or facility. Throughout the literature review, there was limited to no information available discussing litigation outcomes using the experimental and investigational label as an exclusionary provision for coverage; however, in the research done by Harness (1996), there are data showing a rise in claims regarding the commercial payors' refusal to cover testing and devices under their label of investigational and experimental and that a standard of review will depend on what law governs the insurance plan and reimbursement code at issue (Harness, 1996).

Hoffman (1999) discussed and argued that health insurance providers should be required to cover treatments under federal law. This is because many of these commercial insurance coverage policies generate significant debate over the restrictions for healthcare that could potentially put the healthcare provider in a litigation hot seat for not using technology to improve patient outcomes when available (Hoffman, 1999). If we use CPT 92512 as an example, commercial payors state that subjective symptoms and patient-derived assessments supersede objective technological measurements from FDA approved devices. Studies show that there is no correlation between patient-directed assessments, such as the SNOT-20, and objective measurements, such as rhinometry and rhinomanometry (Ansari, Rogister, Lefebvre, Tombu, Poirrier, 2019; Corry, 2006). The objective measurements of acoustic rhinometry (AR) hold the same clinical compatibility and comparability to computed tomography (CT) and are better for

predicting subjective outcomes, as evident by the findings of Mamikoglu, Houser, Akbar, Ng, and Corey (2000), "The correlation of the results of the survey SNOT-20 of objective studies of nasal obstruction and the geometry of the nasal cavities … AR and CT are correlated to each other, but their accuracy is limited compared with that of the clinical diagnosis" (p. 67).

Another point of consideration is the potential for physicians to deceive the third-party payors to treat their patients and ignore the dictations of payors on how to practice medicine. Bogardus, Geist, and Bradley (2004) best summarizes this phenomenon by stating:

> Published reports indicate that physicians sometimes use deceptive tactics with third-party payers. Many physicians appear to be willing to deceive to secure the care that they perceive as necessary, particularly when illnesses are severe and appeals procedures for care denials are burdensome. Physicians whose practices include larger numbers of Medicaid or managed care patients seem more willing to deceive third- party payers than are other physicians. The use of deception has important implications for physician professionalism, patient trust, and rational health policy development. If deception is as widespread as these studies suggest, there may be serious problems in the medical profession and the health care financing systems at the interface between physicians and third-party payers. Deception may be a symptom of a flawed system, in which physicians are asked to implement financing policies that conflict with their primary obligation to the patient. (p. 1842)

In a response to the restriction of healthcare by limited reimbursement, Alexander, Werner, Fagerlin, and Ubel (2003) found support for physicians' deception practices towards insurance companies among 700 prospective jurors from a sample group of consumers in Philadelphia. Participants were asked in a survey whether, in response to restriction of health

care, a physician should (1) accept restriction, (2) appeal restriction, or (3) misrepresent a patient's condition to obtain the desired service from a third-party payor. The responses were mixed, with a proportion of respondents reporting that the physician should misrepresent a patient's condition to obtain reimbursement: 26% of respondents sanctioned deception, 70% supported appealing, and 4% supported accepting the insurance company decision (Alexander et al., 2003). Among the 27% of respondents believing physicians have inadequate time to appeal coverage decisions, 50% sanctioned deception (Alexander et al., 2003). Any commercial insurer should consider these findings and readdress the label of experimental and investigational and non-coverage of FDA approved technologies and devices.

CHAPTER III

METHODS

The objectives of this study were to (1) analyze and summarize the different ways of how third-party payors define the label experimental and investigational, (2) examine their criteria factors associated with the coverage determination by studying policies and information provided by medical directors, (3) research and recommend specific policy changes and accommodations according to factors associated with the determination of coverage for CPT 92512. This was a qualitative method study, with content analysis and a convenience sample as the interview portion. The case study was representative of five groups to give an example of the larger market actions and opinions. This case study approach is available for future replication of the research. Specifically, the study includes four phases:

(i). Review and analysis of CPBs of third-party payors for a better understanding of their experimental and investigational label.

(ii). Review of third-party payor policies about the reimbursement of FDA approved medical devices covered under the current CMS guidelines for CPT 92512.

(iii). Interviews with medical directors and policy experts to understand how third-party payors define the label experimental and investigational and their criteria factors associated with the coverage determination.

(iv). The clinical and economic benefits of coverage calculations and patient selection for surgery based on CMS claims data, the Medicare national average reimbursement for CPT 92512.

Content Analysis of CPBs, CMS Resources, and Practice Guidelines and Statements

The method that this study used to gather information involved the collection of data via the review of the CPBs and websites of the third-party payors that the study examined, summary reports of CMS claims data, guidelines from professional organizations, and consensus practice statements of physician groups. This allowed the researcher to gain a better understanding of the coverage policies related to the reliability of the documents being used as data sources. The review of documents allowed a glimpse from a different perspective or point of view of the comparisons and contrasts made among the third-party payers and other organizations associated with reimbursement and coverage policies. The disadvantage of this particular method was the quality of the documents and access.

This study used a content analysis of CPBs with a qualitative portion to assess various factors used by third-party payors in the determination of coverage for CPT 92512. The research design was the best choice for this type of study, as it was a one-time review to capture information for proposed standardization of policies for the defined technology, reimbursement, and clinical use selection criteria by way of CPB availability online.

Quantitative data collection was in numerical forms that were converted or processed into mathematical information in the form of statistics to give it a meaningful conclusion of the results. The quantitative data collection techniques made use of larger sample sizes because of its measurable nature.

Qualitative Data Collection

Data collection is described by Baxter and Jack (2008) as the "process of gathering and measuring information on variables of interest, in an established systematic fashion that enables one to answer queries, stated research questions, test hypotheses, and evaluate outcomes" (p.

544). It aids in the search for answers to questions, resolutions, and possible changes. Multiple approaches are available when considering qualitative research, as in the study that focuses on explaining, understanding, or predicting human behavior, and are ideal for research and useful for exploring responses to particular clinical scenarios or associations. A qualitative study with a case study component helps researchers to understand complex phenomena within their context. When the approach is applied correctly, it becomes a valuable method for health science research to develop theory, evaluate programs, and develop interventions (Baxter & Jack, 2008).

As part of this research, qualitative data were obtained in the form of a questionnaire and were more structured in nature based on a certain set of questions were prepared before the interview by way of a telephone conversation (see Appendix A). The advantage of this data collection method was the ability to cast a wider set of opinions because there was no need to travel distances to get the data. The disadvantages of this data collection method were the data may be questionable due to the terms of impartiality from the participants, specifically, the group of medical directors, policymakers from commercial payors, manufacturers, reimbursement experts, and data analysis was restricted by the lack of details, but is still possible.

The qualitative data collection method based on interviews was concerned at getting inside to the factors associated with the label of experimental investigational, as defined by third-party payers, and understanding the line reasons and motivations for them doing so (Cooper & Schindler, 2014). The data collection instrument for this particular research was a structured collection of questions that were distributed via email and served as personal interviews.

Qualitative research enlists the collection of non-numerical data that tends to interpret the meaning to understand a particular issue and hypothesis and healthcare, in this particular case, healthcare policy and factors associated with the label of experimental and investigational

(Cooper & Schindler, 2014). Methods of qualitative research include observation and immersion, interviews, focus groups, content analysis of visual, text materials, and oral history (Cooper & Schindler, 2014). This research allowed the researcher to investigate the meanings associated with the factors determining experimental and investigational, as it related to healthcare policy and reimbursement. It also helped reveal the meaning that informs the action or outcome through interviews of open-ended questions from a small group of medical directors and policy committee members, in addition to the review of content analysis from the website and CPBs of each third-party payor. The advantage of qualitative research is the flexibility, the adaptability to changes in the research environment, and the research can be conducted with minimal to no cost. This portion of the research did not incur any costs.

Data Collection Protocol

According to the policies of the Central Michigan University Institutional Review Board Director of the Office of Research Compliance, the research did not meet the definition of human subject research under the purview of the IRB according to federal regulations.

The research process began by completing an internet search with the following keywords and the insurer name: *rhinometry, rhinomanometry, medical policy, clinical policy bulletin, coverage, reimbursement, experimental and investigational,* and *CPT 92512*. Once the sites and policies were identified, a complete analysis of the clinical policy was completed by reviewing the body of the policy, the references used to write the policy, policy review history, and the demographics of the insurer. Additional exploratory research included CMS claims data, professional guidelines, standards of practice, professional society recommendations for the use of nasal function studies and objective airway measurements in clinical practice from 2014-2019, written policy opinions and guidelines on the use and coverage and reimbursement of CPT

92512, nasal function study, and literature from medical companies discussing the label of investigational and experimental

Once the review was completed, the interview process began. The interview design consisted of discussion and conversation queries to uncover the process and rationale for defining an FDA approved and available medical product as investigational and experimental. A comprehensive analysis comprised of the writings for publication after the data and notes were taken during the review and interviews was completed.

Using a content analysis of CPBs, with a qualitative portion to assess various factors used by third-party payors in the determination of coverage for CPT 92512, the research design was the best choice for this type of study, as it was a one-time review to capture information for proposed standardization of policies for the defined technology, reimbursement, and clinical use selection criteria by way of the CPB availability online.

Review of Third-Party Websites

A review of third-party payors started at the home page with the *About Us* section and then located the search box on the main page to find the medical policies. The transition from the home page to the medical plicy and/or clinical policy page to the policy information allowed the researcher to verify the presence or absence of a policy. Within the medical policy page, the researcher found the policy by entering keywords *rhinometry* or *92512*. This automatically pulled up the experimental and investigational policy, listing the origination date, the dates of policy reviews, the last date of review, the outcome of the reviews, the determination policy and details to substantiate the experimental and investigations label, and the cited references used to determine the experimental and investigational label. Alternatively, the websites required the search to start at or directed one to the provider tab and page, then click the accept icon, type in

keywords, and then the medical policy information appeared. In addition to the CPB, a search for an experimental and investigational policy was conducted for each payor.

Reviewing third-party payor websites was an excellent way to find policies regarding coverage, the number of enrollees or members, provider services, provider location, cooperative information, and financial reports that determine the size of the company. It also revealed availability by state based on particular circumstances for summary information to highlight the key provisions and benefits, to include medical policies.

Review of CPBs

A content analysis of CPBs examined factors associated with insurance coverage of CPT 92512, nasal function study, and the use of the label experimental and investigational among third-party payors. Data for this study came from systematic reviews of relevant literature and clinical policies within GM Instruments, Ltd., third party payors, state agencies that determine Medicaid policy, and government agencies. Additionally, the research came from a systematical review of CPBs and literature to understand how third-party payors define FDA approved products and services as investigational versus non-investigational, and what facts may be associated with the definition and the impact it has on patient care (Blair-Holbein, 2009).

Review of CMS Data Claims

The Research Data Assistance Center (ResDAC) is a CMS contractor that provides free assistance to researchers interested in the CMS data. As a CMS contractor, they assist in academic, non-profit, for-profit, and government researchers. An internet search of key terms *CMS data* and *claims history* resulted in a link and description of a company named ResDAC. Within the site, a query was sent to the general mailbox asking for assistance in accessing claims

data history and CMS policies for coverage determination of CPT 92512. Within a few days, a data analyst responded by email with information directing the researcher to public use files that were downloaded directly off CMS's website for free; if the following options did not work, there were paid options. The public options used for the data search were Medicare Provider and Utilization Data, Part B National Summary Data, and Physician/Supplier Procedure Summary. Within the file titled Medicare Provider and Utilization Data, only the Physician and Other Supplier file listed the Healthcare Common Procedure Coding System (HCPC), which is part of a two-part standardized coding system used to process claims for insurance payments to non-physician services by CMS. The other two files organized utilization by the respective payment system, e.g. CPT, Inpatient has Diagnosis Related Group (DRG), outpatient has APC, etc.

Through the assistance of ResDac, CMS data revealed the billing activity of CPT 92512 by year and drilled down to medical specialty. The data supported the relevance of the code with a national reimbursement average, detailed MAC reimbursement, specialty use, and length of activity, and provided evidence of the CMS definition of experimental and investigational and the value of the test through continued use and billing of the code.

Review of Professional Society Clinical Guidelines and Recommendations

The purpose of clinical practice guidelines is to assist in developing or reforming a professional society policy offered as a model of care, or clinical algorithm, and is adapted by which society review boards determine how they will perform. These guidelines are especially important when annual meetings are not available or feasible for various reasons.

Guidelines begin with general information on the society and subcategories for specific disease processes and are systematically viewed as assisting the healthcare provider and patient in decisions for appropriate healthcare based on certain circumstances. Additional information is

available on the formation and operation of the association, to include evaluations and disciplinary approaches. These types of policies are used by third-party payors to determine reimbursement and coverage policy coordinates for writing the CPB. Although they are not fixed protocols, they due lend credulity as recommendations based on evidence and reviews of professional medical articles. Processional society guidelines are standards and quality of care, are available on any professional society website, and ares not a substitute for physician advice. The review of these types of documents is essential in understanding the reasons why a third-party payor may define an FDA approved technology as experimental and investigational and will be completed for this study from the following societies: AAO-HNS, AAAAI, AMA, and AASM.

This study analyzed guidelines through an internet search of each website of a specialty that would do a nasal function study. Once on the website, key terms from the research were entered to populate the guidelines. The search found guidelines from the professional academies for allergy, ENT, and plastic surgery and presented in the results.

Review of Position Statements

A position statement is like a thesis or goal and describes one side of an arguable viewpoint, in this case, by a healthcare group. When writing a position statement, the author(s) gather a list of reasons to support a particular viewpoint and make their stand clear to the audience, also highlighting potential role changes and adaptations for the future. These are often published in professional journals as a supplement to the journal such as Rhinology, on medical specialty websites, and are referenced by third-party payors when writing CPBs. For this study, these were reviewed for defending and supporting the reason for the change in policy to omit the label of experimental and investigational, as societies, such as the AMA (2019) and AASM

(2019) support the use of objective nasal measurements in clinical practice for particular patient populations.

An analysis of positions statements was conducted from websites allowing access to documents and research supporting the use of nasal function studies for patient care. Documents were found from pediatric and allery meetings and presented in Table 10.

Healthcare Financial Aspects and Implications

An analysis of the healthcare financial aspects and implications of the experimental and investigational label was conducted based on information from professional society information and CMS claims data links sent to the researcher from ResDAC. The ENT community had a link accessing the number of sinus procedures performed annually, with the range of costs. This information was used in conjunction with the national average reimbursement amounts to conclude the impact of the experimental and investigable label on healthcare systems and healthcare delivery.

Interviews

The recruitment email requested participation in a study exploring the factors associated with the experimental and investigational label for CPT 92512. The subject matter experts (SMEs) were recruited based on expertise on the topic or utilization and familiarity of the technology associated with the code, such as acoustic rhinometry or rhinomanometry; the billing code; and CPBs. Respondents were provided information on the nature of the study and the required time commitment, as well as their ability to opt-out of the study if they chose during any point of the study.

After a systematic review of third-party payor CPBs and website content defining the term experimental and investigational, an interview of five to seven SMEs occurred as part of the study. SMEs were provided confidentiality by insurer name, participant name, and professional title or otherwise by way of a letter stating specifically that this will be communicated in the letter to them by way of email; however, the opinions, testimony, and policies were publicly available on their websites, as are the names of the SMEs. They were to be known experts in their professions and whatever they shared with me was publicly available once published in my dissertation.

The chosen SMEs were a combination of a commercial payor medical director or policy manager, a physician who uses the CPT code 92512 and the technology associated with the code, or a practice administrator. The selection of SMEs was derived by the insurer websites that covered or did not cover CPT 92512, were from past and current industry relationships, were opinion leaders in their field to discuss the problem with the experimental and investigational label, and were able to share ideas of how the label can be changed to improve healthcare delivery and policy.

To conduct the interview, a set number of questions and an information sheet were sent to each participant by way of email, and they responded in writing. The email to the participant stated that the study was being conducted on behalf of CMU DHA student Karen Davidson, participation was voluntary, and by submitting answers in writing, they were in agreement of participating and consent to participation. The participants were assured confidentiality as they were asked to fax their written responses to 410-721-8061. They were permitted to mail responses to 2417 Heather Stone Dr. Gambrills, Maryland, 21054. Some chose to email them instead, and unless cryptic, they did so knowing the lack of security within the email system and

did so at their will. Additionally, they were informed that their responses were to remain confidential by being placed under a locked file cabinet in a locked office. The responses will be kept indefinitely. The responses contained a theme and theme statements in an appendix of the dissertation to show the various views within the policy industry and for potential positive policy implementation and changes to the current coverage opinions. All policies, statements, leadership teams, coverage determinations, and experimental and investigational definitions were for public viewing on the commercial payor websites and that of the manufacturer.

Institutional Review Board

Informed consent forms were given to all potential participants. The informed consent form included a brief discussion of the study background and its purpose. The tasks involved for a participant, as well as how the data collection was commenced and progressed, were delineated in the form. The possible risks, consequences, and procedures on withdrawal from the study were presented. It was specifically noted in the informed consent that participation in the study was purely voluntary, and withdrawal at any time was possible without any financial, emotional, or physical consequences to the participants. In case of withdrawal, the participant had to inform the researcher about the intention to withdraw, and all information from the requesting participant was excluded from further analysis. Verbal consent was obtained from each participant before any actual data collection was started. Consequently, participants who did not consent were not allowed to proceed through the data collection process.

The signed consent worked as an email response for an interview by documenting and logging the SME, date, time, a note that the prescribed script was used, and a record of the participant's response. Also, the researcher indicated in writing that the consent form was mailed and explained to the participant before receiving the participant's consent that the

participant has knowledge of the research project and appeared to understand it. This was the alternative to emailing the consent to be returned to the researcher.

The co-investigator was familiar with the ENT market and uses the technology, based on previous conversations regarding the type of surgical procedures that would use the technology and code in the diagnosis of sinus disease. The SMEs had previously communicated with the co-investigator during professional meetings and conversations regarding CPT 92512. It required that they were knowledgeable of or on the committee for writing the CPBs. Questions that were asked during the interview are included in Appendix A. There were two participants who requested a follow-up phone call and conversation related to their answers for additional information.

Data Sources and Sampling

For this study, the CPB was used as the unit of analysis. Data for this case study came from reviews of websites, relevant archival CPBs, current literature, and clinical policies within a private medical device company, third-party payors, government agencies, and integrated delivery networks. Literature review findings were complemented with semi-structured interviews from those who wrote CPBs, accepted reimbursement under the CPT code 92512, used the technology, and understood the literature results to better understand what the data reveals and how third-party payors defined investigational versus non-investigational labels of FDA approved products and services.

Retrieval of CPBs and third-party demographics occurred during a website search of keywords, such as CPT 92512, reimbursement, acoustic rhinometry reimbursement, nasal function study, rhinomanometry, and CPB, and medical policy searches on third party payor

websites. CPBs were pulled and reviewed from the websites of third-party payors, the FDA, CMS, and professional societies.

The sample was derived from a globally populated list of third-party healthcare payors in the United States retrieved from the National Association of Insurance Commissioners (NAIC) (2013) website that lists the top healthcare insurers. The insurers also had policy personnel writing reimbursement and clinical policies for commercial healthcare policy plans. The sample size was decreased to 63 for policy review and five SMEs for interviews. To allow for an adequate review to take place, to ensure a positive response rate due to current relationships within the insurance companies, and to minimize the excessive amounts of data interpretation that came from multiple policies from each insurer, 63 was the best number for the research. The sampling of third-party payors consisted of larger carriers. From a search of key terms, the largest healthcare insurers in the United States included UnitedHealthcare Group, Aetna, Cigna, BCBS, Anthem/Wellpoint, Kaiser Permanente, Humana, Health Care Service Corporation for BCBS, Centene/HCSC, Independence Health Group/ BCBS, GuideWell/BCBS, Molina, and HighMark The number of insurers was based on the list comprised of the top insurers from the search and access to CPBs and coverage verification. The Critical Appraisal Skills Programme (CASP, 2018) form and data extraction form were the data extraction instrument that identified eligible research studies to ensure eligibility and quantity with proper screening.

The data extraction instrument identified eligible CPB referenced studies to ensure eligibility and quantity with proper screening. Study eligibility was conducted by screening CPBs/medical policies, reviewing literature abstracts, reading the full text, analysis of the studies' subjects, results and conclusions, and retrieving information related to the topic. The inclusion criteria consisted of SMEs, the timeframe of the literature of 10 years, study focus,

researched methods, and features. The exclusion criteria consisted of non-English language, originality of work, and type of article (commentary, editorial, paper conference, non-peer-reviewed articles).

Two data extraction forms/instruments were used; the CASP form and the data extraction form. The CASP form identified a clear statement of the aims of the research, the appropriateness of the qualitative methodology, the research design to address the aims of the research, the recruitment strategy in selecting the participants to address the aim of the research question(s), the clarity of the method of data collection, the consideration of the relationship between the researchers and participants, the consideration of ethical issues, the sufficiency of rigorous data analysis, a clear statement of findings, and the value of the research.

The data extraction form summarized the data from the individual studies and CPBs related to the data needed to answer the research question and was designed to provide information about the databases searched, the source, the purpose of the study, the duration of the study, key interventions used, data analysis methods, data collection procedures, the timing of intervention strategies, and finally, the outcomes of the study reviewed. Study eligibility was conducted by screening CPBs/medical policies; reviewing literature abstracts; reading the full text; analyzing the studies' subjects, results, and conclusion; and retrieving information related to the topic.

The interview design consisted of questions to uncover the process and rationale for defining an FDA approved available medical product as investigational and experimental, observing the utilization flow of the use and knowledge of the label and code, and the interconnectedness of the five groups. With literature that was limited to controlled case series, which clinical policies, interventions, disease definition, and outcomes measure that was not

standardized, participants were asked to define their methods, opinions, and definitions of the experimental and investigational label for use of FDA approved medical devices.

Review of CMS Data Claims

The ResDAC is a CMS contractor that provides free assistance to researchers interested in the CMS data. As a CMS contractor, they assist in academic, non-profit, for-profit, and government researchers. Through the assistance of ResDac, CMS data revealed the billing activity of CPT code 92512. The data supported the relevance of the code with a national reimbursement average, detailed MAC reimbursement, specialty use, length of activity, and evidence of the CMS definition of experimental and investigational and the value of the test through continued use and billing of the code

Professional Society Clinical Guidelines and Recommendations

The purpose of clinical practice guidelines is to assist in developing or reforming a professional society policy offered as a model of care or clinical algorithm and adapted by which a society review board determines how they will perform. These guidelines are especially important when annual meetings are not available or feasible for various reasons.

Guidelines begin with general information on the society and subcategories for specific disease processes and are systematically viewed as assisting the healthcare provider and patient in decisions for appropriate healthcare based on certain circumstances. Additional information is available on the formation and operation of the association, to include evaluations and disciplinary approaches. These types of policies are used by third-party payors for determining reimbursement and coverage policy coordinate for writing the CPB. Although they are not fixed protocols, they due lend credulity, as recommendations are based on evidence and reviews of

professional medical articles. Processional society guidelines are standards and quality of care, are available on any professional society website, and are not a substitute for physician advice.

The review of these types of documents is essential in understanding the reasons why a third-party payor may define an FDA approved technology as experimental and investigational. The review will be completed for this study from the following societies: AAO-HNS, AAAAI, AMA, and AASM. As part of the research, professional society guidelines and position statements were studied and tabulated.

Position Statements

A position statement is like a thesis or goal and describes one side of an arguable viewpoint, in this case, by a healthcare group. When writing a position statement, the author(s) gather a list of reasons to support a particular viewpoint, make their stand clear to the audience, and highlight potential role changes and adaptations for the future. These are often published in professional journals as a supplement to a journal such as Rhinology, on medical specialty websites, and are referenced by third-party payors when writing CPBs. For this study, these were reviewed for defending and supporting the reason for the change in policy to omit the label of experimental and investigational, as societies, such as the AMA (2019) and AASM (2019), support the use of objective nasal measurements in clinical practice for particular patient populations.

Policy Opinions for Coverage

In healthcare policy, a decision has to be made whether innovation, technology, or a procedure is necessary or not necessary, and this depends on who is doing the deciding (Collier, 2012). Healthcare opinions on whether a particular test or service is medically necessary, based

on a subjective opinion for policy and coverage, are widely varied among commercial insurers (Aetna, 2019; UnitedHealthcare Group, 2019b). Equally divisive in these policy opinions are the opinions of who should not be involved in making these decisions and in writing CPBs (Collier, 2012). It should be noted that medical necessity should be determined by the healthcare provider and the patient, not a government entity or capitalistic, profitable company. Many of the panels that write CPBs and policy opinions for coverage, or *expert committees,* are comprised of industry experts that review scientific data to determine which test procedure and to whom it is necessary (Aetna, 2019; Collier, 2012). The subjects of opinions create havoc in healthcare delivery, as the message is incongruent and has a baseless foundation because of old data or opinions authored outside of the United States. Is the opinion of commercial providers that they should be the ones offering policy opinion for coverage without necessarily involving healthcare providers as medical experts? Many feel the commercial payor creates a bureaucratic exercise in saving money and creates an unfair and unreasonable process based on their perceived evidence. As part of this research and study, acoustic rhinometry fell into this category due to the inconsistencies of coverage for CPT 92512. It is the review of these documents that defend and suggest the elimination of the experimental and investigational label (Collier, 2012).

Clinical Validation for the Non-Use of the Experimental and Investigational Label

Clinical validation was defined as documentation of a diagnosis as a matter of record that was substantiated by clinical criteria accepted by the medical community. Accepted clinical criteria came from evidenced-based medicine, consensus, or professional guidelines. In the absence of clinical validation of sources, a less objective test of validity was acceptable and sufficient for establishing the diagnosis. For example, the normal curve for nasal airway measurements, also known as the cross-sectional mean area, was established by rhinology

experts; however, policies were stating that subjective, patient self-directed assessment tools were *more* standard than technology and innovation (GM Instruments, 2019). The argument of less objective testing as a valid source for diagnostic purposes seemed less valid when applying the concept to professional claims. The industry argument remains that of eliminating the experimental and investigational label to improve valid diagnostic measures.

Validity and Reliability

Validity to the study was contributed by the questions intended for the topic that resulted in a well-founded measurement and corresponded to the findings as to the data from the CPB, CMS data, and professional guideline, and statements have not changed during the time of the research, nor will it change in the foreseeable future without legislative action. Suggestions and edits of the SME questions by the committee improved the qualitative portion of the study for a better understanding of the results relevant for the understanding of the problem.

The reliability of the study was maintained, as the findings obtained by other researchers using the same or more than one assessment method with the same group would result in similar findings and the same conclusions.

Limitations to the study were access to proprietary information, proprietary CPB implementation processes; the inability to obtain responses that could not be utilized; access to primary interview targets, such as medical directors, medical affairs review boards, CMS, and the FDA; a lack of CMS national determination policies specific to CPT 92512; and lack of access to the listing structure of the body of work chronologically and when they were published. A limitation of this approach was that it inhibited continuity in the arguments, and in some instances, undermined the coherence of the work.

CHAPTER IV

RESULTS

CPB Review and Analysis

This section presents the findings of the CPB content analysis. Fourteen health insurers, comprising 54.5% of the national healthcare market, and 50 CPBs included two companies and 23 policies that defined CPT 92512 as experimental and investigational (see Tables 3 and 4). In a market of 176.9MM enrollees and $1.015T in revenue, 85% ($N = 12$) of the payors follow the CMS gold standard of coverage, with a 92% rate ($N = 13$) of having an established experimental and investigational definition and CB policy.

Table 3. Coverage Policies for CPT 92512 for 54% of Healthcare Market

Insurance Company	% of US Healthcare Market Share	Number of Enrollees/ Members	Annual Revenue	Cover CPT 92512?	E & I Label and CPB Policy
United Health Group	12.36	38.0MM	$242.15B	Yes	Yes
Anthem/WellPoint	8.69	31.6MM	$92.10B	Yes	Yes
Kaiser Permanente	7.46	12.2MM	$56.30B	Yes	Yes
Humana	5.10	16.6MM	$56.90B	Yes	Yes
Aetna	5.00	22.1MM	$245.00B	No	Yes
Health Care Service Corporation for BCBS	3.00	15.0MM	$35.90B	No	Yes
Centene/HCSC	2.80	14.0MM	$72.30B	Yes	Yes
Cigna	2.50	3.6MM	$129.70B	Yes	No
Independence Health Group/ BCBS	1.60	4.8MM	$16.30B	Yes	Yes
Blue Shield of California	1.60	4.0MM	$17.70B	Yes	Yes
GuideWell/ BCBS	1.50	6.5MM	$15.00B	Yes	Yes
Molina	1.50	3.5MM	$17.00B	Yes	Yes
HighMark	1.40	5.0MM	$18.80B	Yes	Yes

In an expanded search of 50 CPBs, 40 CPBs were available online, and those not available were verified by the insurer provider services by calling the corporate number. The call to provider services was made to ask if there was reimbursement for CPT 92512.

The study of CPBs showed that 58% ($N = 29$) of the health insurers did not consider CPT 92512 as experimental and investigational and had a coverage policy to support reimbursement, 36% ($N = 18$) considered CPT 92512 as experimental and investigational and lacked coverage for the service of nasal function study, and 6% ($N = 3$) of the CPBs considered CPT 92512 as experimental and investigational, with coverage dependent on the benefit plan language or requiring prior authorization to be covered (see Table 4).

Table 4. Expanded Coverage Determination of 50 CPBs

Company	Location	Covers 92512
UnitedHealth Group	Minneapolis, MN	Yes
Kaiser Foundation Group	Oakland, CA	Yes*
Wellpoint Inc. Group/Anthem	Indianapolis, IN	Yes*
Aetna Group	Hartford, CT	No
Humana Group	Lexington, KY	Yes
HCSC Health Care Service Corp	Chicago, IL	No
Cigna Health Group	Bloomfield, CT	Yes*
Highmark Group-Blue Shield	Pittsburgh, PA	Yes*/No*
Highmark Group-Blue Shield	State College, PA	Yes*/No*
Highmark Group-Blue Shield	Camp Hill, PA	Yes*/No*
Blue Shield of California Group	San Francisco, CA	Yes
Independence Blue Cross Group-Commercial and Medicare Adv	Philadelphia, PA	No*/Yes*
Centene Corp Group	St. Louis, MO	Yes/Yes
HIP Insurance Group/Emblem Health	New York, NY	No
BCBS of New Jersey Group	Newark, NJ	No
BCBS of Michigan Group	Detroit, MI	Yes
Guidewell Mutual Holdings Group- 4 of the Florida Blues	Florida	Yes
Guidewell Holdings Group-Florida Blue	Jacksonville, FL	Yes
California Physicians Service, DBA BCBS of California	San Francisco, CA	Yes*
Wellcare Group	Tampa, FL	Yes*
Carefirst Inc. Group	Baltimore, MD	Yes

Table 4. Expanded Coverage Determination of 50 CPBs (continued)

Health Net of California	Woodland Hills, CA	No*
Molina Healthcare Inc Group	LongBeach, CA	Yes
UHC of California	Cypress, CA	Yes
Lifetime Healthcare Group/Excellus BCBS MC & Comm. Cent. NY	Rochester, NY	Yes
BCBCS Massachusetts Group	Boston, MA	No
Metropolitan Group/Met Life	Chicago, IL	Yes
Cambia Health Solutions, Inc/Regence BCBS of Oregon & Utah	Portland, OR	Yes
Louisiana Healthcare Connection Medicaid and LaCHIP)	Baton Rouge, LA	Yes
Premera BC	Mountlake Terrace, WA	Yes
Care Oregon	Portland, OR	Yes
Wellmark	Des Moine, IA	Yes
BCBS of Kansas	Wichita, KS	No
BCBS of IN	Indianapolis, IN	No
BCBS of Massachusetts	Quincy, MA	No
BCBS of Tennessee	Chattanooga, TN	No
Capitol BCBS	Philadelphia, PA	No
BCBS Rhode Island	Providence, RI	No*
BC of Northeastern PA	Wilkes-Barre, PA	No
Emblem Health	New York, NY	No
Emblem Health-GHI	New York, NY	No
Emblem Health-HIP	New York, NY	No
BCBS of Michigan	Lansing, MI	Yes
BCBS of Idaho	Meridian, ID	No
Anthem BCBS of CT	Wallingford, CT	No
Anthem BCBS of Indiana	Lafayette, IN	No
BCBS National Association	Chicago, IL	Yes
Fallon Health	Westchester, MA	Yes
CMS	Baltimore, MD	Yes

* denotes coverage determinations dependent on benefit plan.

The research collected geographical information of all payors with a CPBs, and the results found different geographical coverage determinations based on the payor market that is consistent with the distribution of all payors (see Table 5). Of the commercial payors that covered CPT 92512, 10% ($N = 5$) were located in the Northeast, 22% ($N = 11$) were located in the Midwest, 16% ($N = 8$) were located in the West, and 10% ($N = 5$) were located in the Southern portion of the United States. Of the of commercial payors that considered CPT 92512

as experimental and investigational, 18% ($N = 9$) were located in the Northeast, 14% ($N = 7$) were located in the Midwest, 2% ($N = 1$) were located in the West, and 2% ($N = 1$) were located in the South. Three commercial payors (6%) covered CPT 92512 with considerations that are related to the benefit plan, and Medicare Advantage policies 2% ($N = 1$) were each located in the Northeast, Midwest, and the West (see Table 6). The coverage determination from commercial payors and their geographical location is consistent with the level of technology adoption by providers and the use of nasal function testing equipment based on the number of claims filed.

Table 5. Geographical Areas and Coverage Determination Using the Experimental and Investigational Label

U.S. Geographical Area	Coverage for CPT 92512	Non-coverage for CPT 92512	Coverage of CPT 92512 with considerations
Northeast	10%	18%	2%
Midwest	22%	14%	2%
West	16%	2%	2%
South	10%	2%	0%

The publication date of the CPBs of insurers using the experimental and investigational label for coverage determination ranged from 1985 to 2014 (see Table 6). The average age of the CPB among commercial payors was 15 years, with an average time reviewed 11.17 times, and an average of 28 cited references as the foundation of the written policy.

Table 6. CPB Age, Review, and Citation History by Insurer with Experimental and Investigational Label

Company	Location	Date of Original CPB	Age of Policy (CPB) Years	Date of Last Review	Number of Reviews	Number of Citations
Aetna Group	Hartford, CT	3/01/2005	15	1/27/2020	17	83
HCSC Health Care Service Corp/ BCBS of Illinois	Chicago, IL	1/01/1990	30	9/30/2018	11	38
BCBS of New Jersey Group	Newark, NJ	1/28/2014	6	10/08/2019	Unkn	32
BCBCS Massachusetts Group	Boston, MA	4/1/2007	12	4/01/2012	10	15
BCBS of Kansas	Wichita, KS	Unkn	11	Unkn	Unkn	Unkn
BCBS of Indiana	Indianapolis, IN	1/15/2009	Unkn	Unkn	Unkn	Unkn
BCBS of Massachusetts	Quincy, MA	4/01/2007	12	4/01/2012	10	15
BCBS of Tennessee	Chattanooga, TN	8/01/1985	35	5/09/2019	35	8
Capitol BCBS	Philadelphia, PA	3/1/2012	7	4/29/2019	9	23
BCBS Rhode Island	Providence, RI	12/01/2008	12	11/5/2019	10	10

BCBS National Association

An in-depth search of the 14 companies and subsidiary websites and their CPBs found a more inconsistent pattern of non-coverage of BCBS subsidiaries outside of the BCBS National Association than from all other commercial payors. BCBS consists of 26 subsidiaries, of which 17 coverage determinations were available for analysis (see Table 7). The data showed that even though the BCBS National Association recognized coverage and reimbursement of CPT 92512, the subsidiaries write their subjective policies. From the findings, 35% ($N = 6$) of the subsidiaries cover and reimburse the code, 47% ($N = 8$) do not, and 18% ($N = 3$) have coverage considerations.

Table 7. BCBS Subsidiary Policy Determinations of CPT 92512

Company	Coverage for 92512	Policy Number/Title	Date of Original CPB	Date of Last Review	Number of Reviews
BCBS National Association	Yes	NA	NA	NA	NA
Independence Blue Cross Group-Commercial and Medicare Advantage	Yes*	NA	NA	NA	NA
Horizon BCBS of New Jersey Group	No	78	1/28/2014	10/8/2019	Unkn
BCBCS Massachusetts Group	No	586	April 2007	4/1/2012	12
BCBS of Kansas	No	Unable to find a policy	Unkn	Unkn	Unkn
BCBS of Indiana	No	Unable to find a policy	Unkn	Unkn	Unkn
BCBS of Massachusetts	No	586	April 2007	4/1/2012	12
BCBS of Tennessee	No	Rhinomanometry and Acoustic Rhinometry	August 1985	5/9/2019	35
Capitol BCBS	No	MP2.088	3/1/2012	4/29/2019	7
BCBS Rhode Island	No*	Rhinomanometry and Acoustic Optical Rhinmanometry	12/01/2008	11/5/2019	10
BC of Northeastern PA	Yes	NA	NA	NA	NA
BCBS of Michigan	Yes	NA	NA	NA	NA
BCBS of Idaho	Policy Specific	NA	NA	NA	NA
Anthem BCBS of CT	No	Unable to find a policy, but as mentioned in one policy	Unkn	Unkn	Unkn
Anthem BCBS of Indiana	No/Yes*	Unable to find a policy, but website state no prior auth needed	Unkn	Unkn	Unkn
BCBC of Alabama	Yes	NA	NA	NA	NA
BCBS of North Dakota	Yes	NA	NA	NA	NA

*denotes coverage determination dependent on benefit plan.

In 2005, Aetna implemented its CPB Policy 0700 for Rhinometry and Rhinometry as experimental and investigational. Table 8 shows that even though Aetna did not cover the nasal

function study, the results show the number of submitted claims was at its peak. The number of claims in the timeframe of 2005 to 2014 shows the most use of the test, which negates the argument of not using the devices and testing due to lack of reimbursement and the presence of the experimental and investigational label. Although the results are antidotal and reflect 16% of the U.S. population, the message could be extrapolated by the number of claims at its peak.

CMS Claims Data

Many of the CPBs state that coverage may be mandated by applicable legal requirements of a state, the Federal Government, or the CMS members, yet state that CMS does not have a national or local Medicare coverage position, which leads to confusion for a provider and patient; there does not have to be a determination to bill the CPT code that will be paid according to the geographical location in the United States, the RVU, and the Practice Expense (PE). According to the findings from data mining of CMS provider utilization of CPT 92512, Table 8 shows a 19-year history of CMS National Summary Data for CPT 92512 of allowed service, allowed charges, and final reimbursement amounts for 16% (N = 51.9 MM) of the U.S. population over the age of 65.

Table 8. Medicare Provider Utilization Data 2000 – 2018 (CMS, 2020)

Year	Description	Modifier	Allowed Services	Allowed Charges	Payment
2018	Medicine	Total	5,600	$365,183.34	$278,701.12
2017	Medicine	Total	5,592	$371,346.44	$278,957.14
2016	Medicine	Total	5,793	$384,377.06	$294,437.90
2015	Medicine	Total	5,381	$362,325.15	$279,242.92
2014	Medicine	Total	6,423	$433,860.05	$335,165.71
2013	Unavailable	-	-	-	-
2012	Medicine	Total	6,721	$457,419.07	$359,692.61
2011	Medicine	Total	7,100	$496,932.78	$392,915.89
2010	Medicine	Total	5,987	$402,452.10	$317,359.11
2009	Unavailable	-	-	-	-
2008	Unavailable	-	-	-	-
2007	Unavailable	-	-	-	-
2006	Medicine	Total	6,599	$473,703.21	$373,187.74
2005	Medicine	Total	6,901	$480,178.64	$378,407.69
2004	Medicine	Total	6,334	$414,964.10	$326,785.38
2003	Unavailable	-	-	-	-
2002	Medicine	Total	3,486	$234,615.00	$185,294.00
2001	Unavailable	-	-	-	-
2000	Medicine	Total	2,018	$73,233.00	$57,299.00

The results support the argument there does not have to be a determination to bill the CPT code that will be paid according to the geographical location in the United States. Furthermore, the allowed services show a modest trend, before a slight decline in the range of 10% - 16% at the time of many CPB policies and the label of experimental and investigational came to the market, especially with the BCBS subsidiaries in Table 7.

In the Medicare National Coverage Determinations Manual, Chapter 1, Part 1, Section 50, the research found the National Coverage Determination (NCD) for the Ear, Nose and Throat (ENT) specialty where CPT 92512 is used, appears to only cover items of DME or device nature. These items refer to the ENT subspecialties of Otology and Laryngology and include Speech Generating Devices, Electronic Speech Aids, Cochlear Implantation (Effective April 4, 2005),

Tracheostomy Speaking Valve, Oxygen Treatment of Inner Ear/Carbon Therapy, Tinnitus Masking, Cochleostomy with Neurovascular Transplant for Meniere's Disease, and Ultrasonic Surgery.

The research and data mining of CMS claims in Table 9 shows that of the 5,812 service claims submitted in 2018 across all specialties, the data analysis found 50% (N = 2,910) were from ENT, with a low denial rate of 3% (N = 92) and 96% (N = 5,586) of the claims for services paid across all specialties.

Table 9. 2018 CMS Part B National Summary Claims Data by Specialty (CMS, 2020)

Specialty Code	Provider Specialty	Submitted	Denied	Percentage Claims Denied	Percentage Claims by Specialty
1	General Practice	3	3	100%	< 1%
3	Allergy	395	17	4%	7%
4	ENT	2,910	92	3%	50%
11	Internal Medicine	58	7	12%	1%
13	Neurology	226	5	2%	4%
19	Oral Surgery-Dentist Only	545	47	9%	9%
26	Psychiatry	14	2	14%	< 1%
29	Pulmonology	1,434	41	3%	25%
47	Independent Dx Testing Facility	118	0	0%	2%
50	Nurse Practitioner	6	1	17%	< 1%
66	Rheumatology	2	0	0%	< 1%
72	Pain Management	2	0	0%	< 1%
93	Emergency Medicine	15	1	7%	< 1%
97	Physician Assistant	84	10	12%	1%

In a more thorough analysis of policy and coverage determination, the research revealed a recent policy change in the National Coverage Determination (NCD) and Local Covearge Determination (LCD) by most recently announcing under the Palmetto-GBA LCD policy a revision for Speech Pathology dated 01/01/2020, yet CPT 92512 remained a non-covered experimental and investigational testing code among many of the BCBS subsidiaries and Aetna.

The coverage determination policy under CMS Outpatient Speech-Language Pathology, titled LCD Outpatient Speech-Language, LCD # L34429, Article titled Billing and Coding: Outpatient Speech-Language Pathology, Article # A56868 included modifiers, ICD-10 Codes that Support Medical Necessity and HCPC/CPT codes, including CPT 92512 (see Table 10). Furthermore, coverage was subjected to local carrier discretion, yet there is a 20-year history of national summary data for CPT 92512.

Table 10. New CMS Outpatient Speech-Language Pathology LCD Policy for CPT 92512 (CMS, 2020)

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina

Clinical Practice Guidelines and Professional Statements

The stoical action of policy creation and review offered many of the policies stating a particular clinical statement incorrectly. For example, Kapur et al. (2017) produced the Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea (OSA) in the AASM Clinical Practice Guideline. Upon further review of the practice guidelines, the message was directed towards diagnostic testing and tools for OSA, specifically recommending that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults in the absence of polysomnography or home sleep apnea testing. CPT 92512 was never indicated for, nor promoted as, a tool for diagnosing OSA; however, there was a promotion and education found from one company using CPT 92512 as a form of *diagnosing* OSA, which is incorrect and

against the approved indications from the FDA in 2010. A more recent consensus statement came from the conference of The International Standardization Committee on the Objective Assessment of the Nasal Airway in November 2016. The aim of the conference was to address the existing nasal airway function tests and to take into account physical, mathematical, and technical correctness as a base of international standardization, as well as the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Conclusively, the performance of an objective assessment of the nasal airway should not be underestimated as an element for a reliable relation, especially for professional care in complex cases (see Table 11).

Table 11. Clinical Practice Guidelines and Professional Standards

Professional Society	Statement or Guideline	Guidelines for Use
American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)	No	Several policies speak to use of objective nasal function studies for surgeries, but no direct policy for nasal obstruction
American Medical Association (AMA)	Yes	Objective nasal measurements should be done based on patient history.
American Academy of Sleep Medicine (AASM)	Yes	Objective nasal measurements should be done based on AMA guidelines
American Academy of Allergy, Asthma, and Immunology (AAAAI)	Yes	Guidelines for use in nasal obstruction and provocation testing
American Academy of Dentistry (ADA)	Yes	Dentists can and do play an essential role in sleep-related disorder breathing and should asses the patient and upper airway obstruction
Facial Plastic Surgery Clinics of North America	Yes	Objective measurements should be used for pre- and post-op evaluation of rhinoplasty
5th Pediatric Allergy and Asthma Meeting (PAAM)	Yes	Recommend rhinometry and rhinomanometry for evaluation in children
International Standardization Committee on the Objective Assessment of the Nasal Airway in Riga, 2nd Nov. 2016.	Yes	The performance of an objective assessment of the nasal airway should not be underestimated as an element for a reliable relation, especially for the professional care in complex cases.

Table 12 summarizes the current recommendations and practice statement in detail by the Rhinology EAACI (2011) listed by the device. The three devices are labeled from least to most favorable, as indicated by the number of plus signs. The research findings in the table showed how they are categorically viewed by an allergy organization, the practice by disease location, age group, home care use, and the effectiveness. The analysis showed the need for the devices and the related CPT 92512 code for clinical trials, treatment, provocation studies in the correlation of symptoms, and disease. The CPBs stated an approach of diagnostic purpose; however, the professional guidelines and statements revealed otherwise.

Table 12. Rhinology Guidelines for Objective Measurements (Shusterman et al., 2019)

Diagnostic purposes	PNIF Meter (Peak Inspiratory Flow) Meter	Rhinomanometry	Acoustic rhinometry
- unilateral disease	-	++	++
- correlation with symptoms	+++	+	+
Use in children			
2-6 y	-	+	+++
6-18 y	-	++	+++
Provocation studies	+++	+++	+++
Clinical trials	+++	+++	+++
Home monitoring	+++	-	-
Evaluation of effect of treatment	+++	+++	+++

Note. The plus sign indicates the level of importance, with +++ being the most valued and + being less valued.

Healthcare Financial Aspects and Implications

The clinical and economic benefits of coverage were analyzed and calculated based on CMS claims data, the Medicare national average reimbursement for CPT 92512, the average number of sinus procedures on an annual basis, and the average cost of the procedure. These calculations were used as an example of healthcare savings, as commercial payor reimbursement

amounts and explanation of benefits (EOB) are proprietary and HIPPA compliant, while varied from plan to plan and company to company. The importance of the financial analysis and results demonstrated how coverage for a test could improve the patient selection for successful surgical outcomes and save healthcare dollars for the system.

The results found that the healthcare financial aspects and implications demonstrated unspoken accountability of the commercial payor to test all patients for sinus surgeries for healthcare costs savings to the system; if you pay $1 for an ROI of $6, it would result in a return of the investment of testing and create revenue for an ideal business strategy.

According to the findings, the cost of a sinus procedure is $75 - $20,000, with an average of $4,588, with an estimated 300,000 sinus surgeries per year, totaling $1.3T annually. The research found 12%, or 36,000, annual surgeries are revision cases (see Table 13), meaning that the patient did not have complete relief from their symptoms and required another procedure, and 20% were not surgical candidates. Therefore, if testing is used to identify 20% of patients who are not candidates for surgery, the cost of coverage to the healthcare system by eliminating non-candidates for surgery is decreased to $1.1T (see Table 13).

Table 13. Healthcare Financial Aspects for Covering CPT 92512

# of Sinus Cases Annually (A)	300,000	600,000
Average Cost of Surgery (B)	4,588.00	4,588
Total Annual Cost of Surgery Paid by Payors (C)	$1,376,400,000	$2,752,800,000
# of Sinus Cases Annually (A)	300,000	600,000
Average CMS Reimbursement Rate (D)	$60.37	$60.37
Total Annual Cost to Perform the Test (E)	$18,111,000	$36,222,000
20% rate of non-surgery candidates (G)	60,000	120,000
Average Cost of Surgery (B)	$4,588	$4,588.00
Total Annual Cost Savings to Payors (H)	$275,280,000	$550,560,000
Potential Cost Savings Using CPT 92512 to identify non-candidate (F) H -E = F	$257,169,000	$514,338,000
# of Sinus Cases Annually (A)	300,000	600,000
Proposed CMS Reimbursement Rate (I)	$120	120.00
Total Investment of Payor (K)	$36,000,000	$72,000,000
ROI: For every $1 spent, there is a rate of return of $6 F-E/K = ROI	$6.64	$6.64
Cost of coverage eliminating non-candidates for OR (J) C-H = J	$1,101,120,000	
Overall Percentage of Cost Savings with Proper Patient Selection for Surgery E /H	6.57%	

Table 14. Revision Cases Cost Analysis

# of Sinus Cases Annually (A)	300,000	
Annual Revision Cases of 12% (L)	36,000	
Average Cost of Surgery (B)	$4,588	
Annual Costs to Insurer (M)	$165,168,000	
Investment if Payor Test Savings if used on Revision cases E x .12% (N)	$2,173,320	
Total Costs to Reimburse for all Surgeries (O)	$1,541,568,000	C + M
Total Cost to invest for testing and allow coverage of CPT 92512	$20,284,320	E + N
20% rate of cost savings for revision non-candidates	$308,313,600	O x .20%

Qualitative Results

Of the 11 invitations sent to commercial payor medical directors, reimbursement experts, clinicians, healthcare administrator/CEOs, policy managers, and an executive from the medical device industry, who were chosen based on the designation and reimbursement of CPT 92512 as experiential and investigational, five responded representing, one from each group of SMEs.

Question 1

Question 1: Are you aware of CPT 92512 and coverage in reimbursement policy for any insurer, and is it covered? Why, or why not?

The first question asked a representative from each group their knowledge of coverage determination of CPT 92512, the level of awareness of the code, and reimbursement policy. Figure 4 shows the utilization flow of the code among the groups and how they would address the coverage issues based on their knowledge, which creates the level of awareness and how the label of experimental and investigational was viewed based on the status of coverage. Across all groups and levels of awareness, the knowledge of the code demonstrated an interconnectedness and information sharing for reimbursement.

The third-party payor and manufacturer were aware of the code due to the direct use for reimbursement and in the sales message for providers as an additional revenue stream for the practice. The reimbursement expert had minimal knowledge due to the number of cases, payors, providers, and manufacturers that consult the services of the expert. The healthcare administrator declined to answer, and the provider did not know the policy for coverage, which falls in line with most scenarios. The administrator is the gatekeeper to the practice and will determine who has access to the providers. The administrator is well versed on the policies from a management perspective, yet neutral to manufacturers and will use the experimental and investigational label as an objection to limit access; they are the *hard stop* of the office.

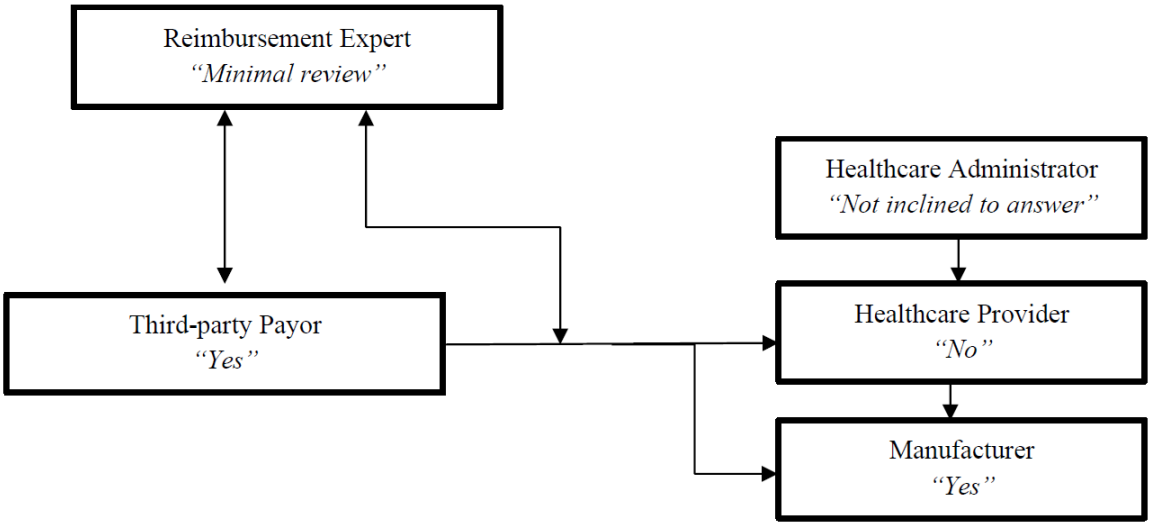

Figure 4. Responses to Survey Question 1

Utilization Flow of Understanding the Experimental and Investigational Label

If the experimental and investigational label is used, the medical device company, healthcare provider, and the reimbursement expert would have to implement a plan to educate the payor of the value of the code, the necessity for testing, and the process to reverse the decisions of the payor. If the experimental and investigational label was not used, the billing and reimbursement process would continue as it normally would with payment for services. If the experimental and investigational label is used within the five groups, a break in care for the patient and lack of access to the test and efficiency in healthcare delivery, as in the case of CPT 92512, was the result. This also explained the interconnectedness of reimbursement and the relationship among the five groups. The trilogy of knowledge, utilization flow, and interconnectedness was found to be an essential factor of the experimental and investigational label use.

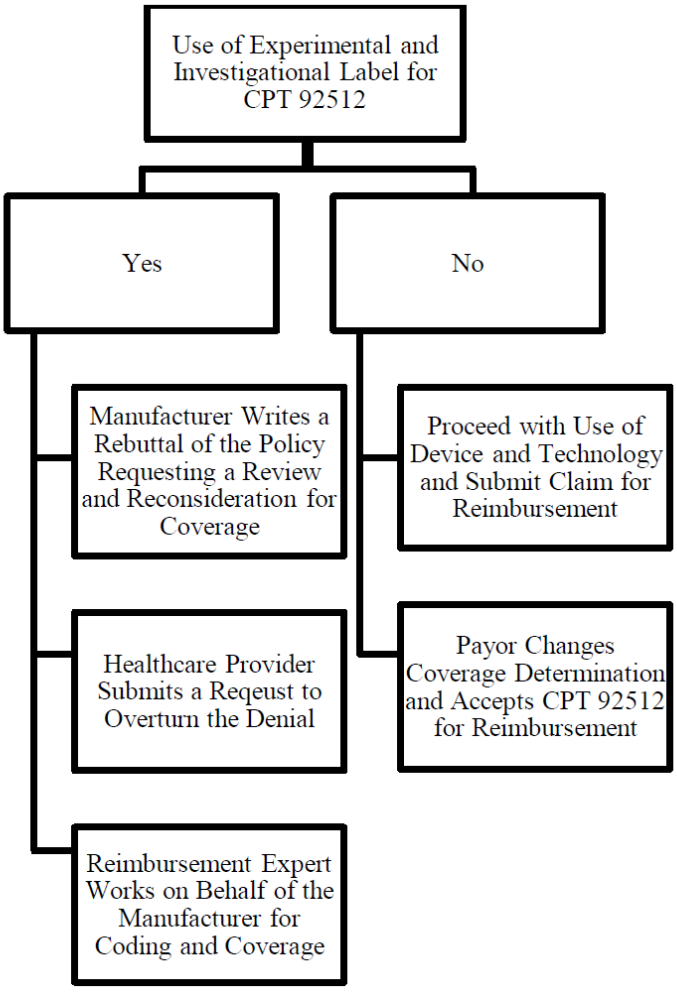

Figure 5. Utilization Flow of Understanding and Use of the Experimental and Investigational Label in the Healthcare System

Interconnectedness

The interconnectedness between the five groups was best explained as a system of intertwining unit of coverage and payment linked across the healthcare system, thus netting the outcomes of working together, yet individually, as in the case of the healthcare facilities, providers, medical device companies, and insurers; however, all are dependent inpatient care (see Figure 5). The use of the experimental and investigational label for non-coverage can disrupt the interdependence of healthcare delivery and the reimbursement system by the

commercial payor, as explained their awareness by stating “We consider CPT code 92512 experimental and investigational because of inadequate evidence in the peer-reviewed published medical literature from well-designed studies demonstrating that incorporation of nasal function studies inpatient management alters that management such that clinical outcomes are improved.” The other groups were less familiar with the coverage policy due to either their use of the code or their level of reimbursement expertise, which was determined by their responses. The medical device industry seemed just as aware of the reimbursement policy, by the level of detail in their answer by stating, “Yes, through my work providing the devices to the clinicians using them.” Most commonly, and as demonstrated by the response, health administrators and healthcare CEOs may not have the awareness, clinical expertise, or consideration of the experimental and investigational liable for two reasons. The first reason is that their primary focus is at the regional or local level or they may not actively participate in the reimbursement policy process for a code or test due to the number of codes and products on the market; the FDA oversees over 165,000 device registrations for 510(k) approved products. The second reason is the level of knowledge and detail of an experimental and investigational label with policy coverage determinations may be overwhelming with their additional roles as an executive.

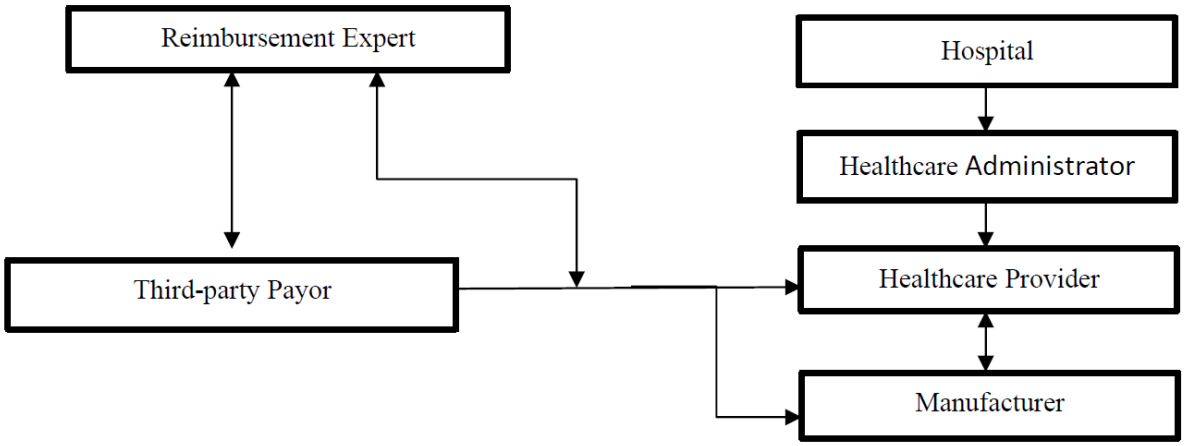

Figure 6. Interconnectedness of Five Groups and the Experimental and Investigational Label

Question 2

Question 2: In your opinion, is there a risk or implication of not covering the code for the test? What would that be?

The group members had a more extended similar opinion when asked about the risk of not covering the code and what those implications would look like in the second question. The commercial payor stated, "Clinical policies are intended to focus on interventions of proven clinical value. The implication of no coverage of unproven interventions is to increase the value of the insurance benefit, and ultimately the quality of medical care." Similar views among the provider, administrator, and medical device industry group with the main theme of high risk and the potential for litigation based on patient awareness and access of the test, yet low risk for covering the test if the demonstrated need was not present as stated by the reimbursement expert. The reimbursement expert stated, "Initial impression, it seems like a test that has low risk or implication of not covered. Would have to demonstrate medical risks/implications to the patient by not doing test, and this may be difficult to across all patients." The variation of understanding risk of coverage, or not, further demonstrates the subjectively of understanding among the

groups and correlates to the subjectivity of policy writing and coverage determinations using the experimental and investigational label.

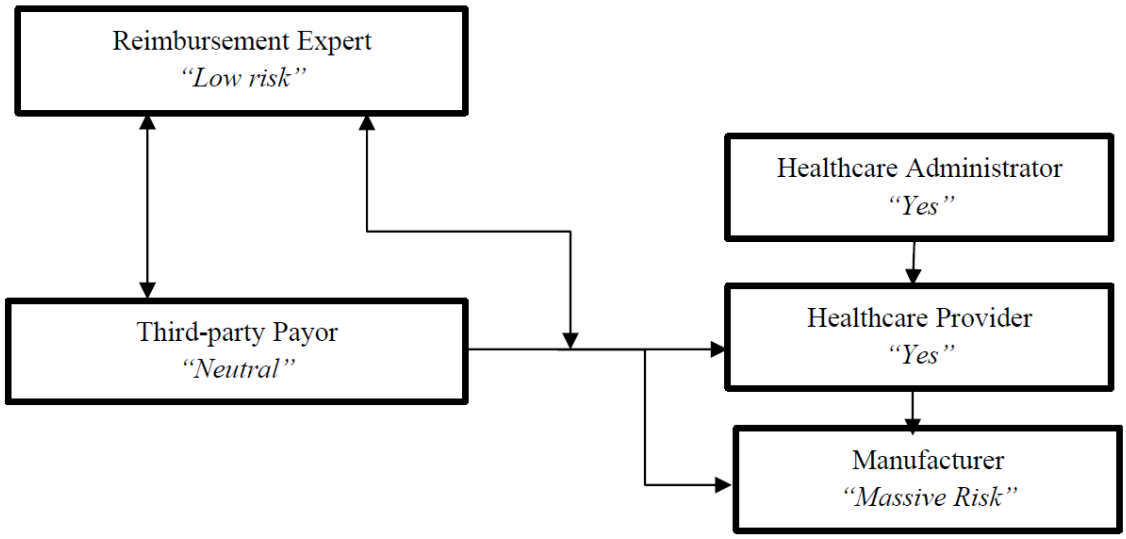

Figure 7. Responses to Survey Question 2

Question 3

Question 3: Are you aware of historical information/data to confirm and support previous coverage of CPT 92512 before the current decision of non-coverage? If so, what, in your opinion, may have changed the policy?

Question three asked of their awareness of historical information or data to confirm and support any previous coverage of CPT 92512 before the current decision of non-coverage and the experimental investigational status of the code. The respondents were then asked their opinion as to what may have happened to change the policy. The commercial payor stated that their published policy has been in place for more than a decade and always designated rhinomanometry, the test covered under CPT 92512, as unproven. Further research and findings indicate that this is partially correct. CPT 92512 was covered by many payors until 2005, when

a bundled billing episode occurred with a non-covered home sleep test device and rhinometry. The result was the experimental/investigational label, directing rhinometry and the sleep test device as experimental and investigational from a large commercial payor in 2005, resulting in a few payors following suit with the experimental and investigational label and non-coverage. The home sleep test device coming to persuade the challenge of reimbursement for their device, in which they won, leaving the rhinometer as non-covered, even with a long market presence history. Due to the number of CPT codes, the reimbursement expert did not complete any research, and therefore, was not aware of any historical information to support the initial coverage. The clinician was not aware, as they do not get that information, which, again, will influence the way they practice and cause the potential chaos in the office from a medical billing and patient access perspective. As for the healthcare administrator, they stated that this would be more of an insurance company answer and not theirs, which again can break the line of interconnectedness and communication as it relates to the experimental/investigational label. The group most aware of historical information and coverage was the medical device industry, and their reply was,

> Yes. Ignorance of the importance of objective measurements of function/dysfunction before selecting a treatment to change nasal function/dysfunction. Short-sighted situational cost savings while ignoring massive savings in both proper avoidance of over-treating, and even larger insurance savings of properly identifying the population that needs treatment (reduction of cardiac issues, stroke, ED, etc. etc.) and proper treatment outcome measures to further hone treatment selection.

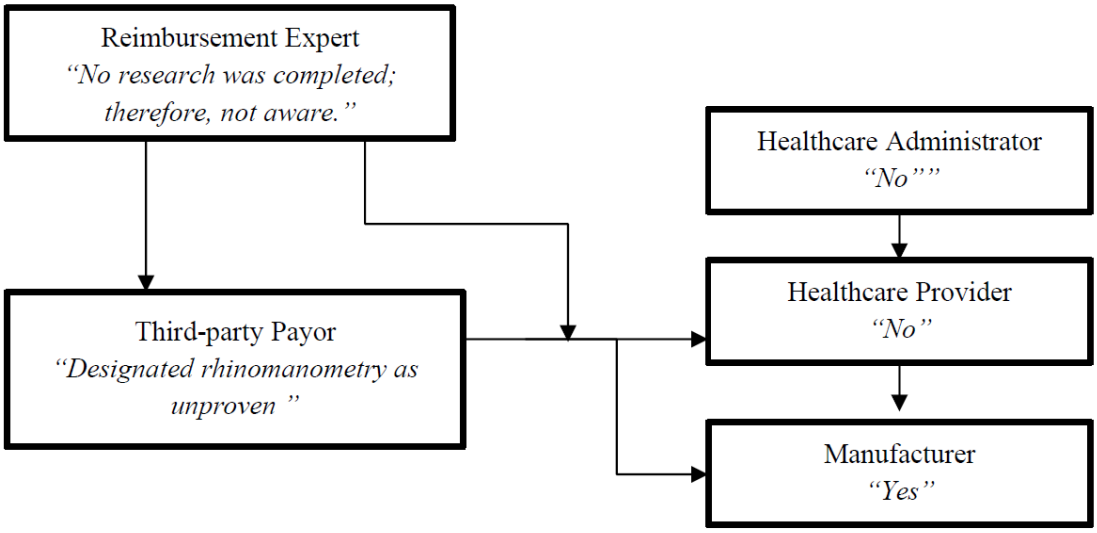

Figure 8. Responses to Survey Question 3

Question 4

Question 4: When you received the invitation for the interview, were you aware of how often the policy is reviewed? If, so, how often?

To investigate the level of awareness in policy review and frequency in Question 4, we found a consensus of the payor and reimbursement expert agreeing on annual reviews; however, the clinician, the healthcare administrator, and the medical device industry were less aware of the policy review frequency. The reimbursement expert, detailed in their answer, stated,

> Policies should be reviewed annually; however, there are circumstances which affect timing. Such as: new and significant clinical documentation becomes available (may review sooner), appeals department or other payer decision-maker determines a review is necessary, also older policies may be archived and that means that routine reviews are no longer scheduled and will only be reopened if data becomes available or requested to reopen for review.

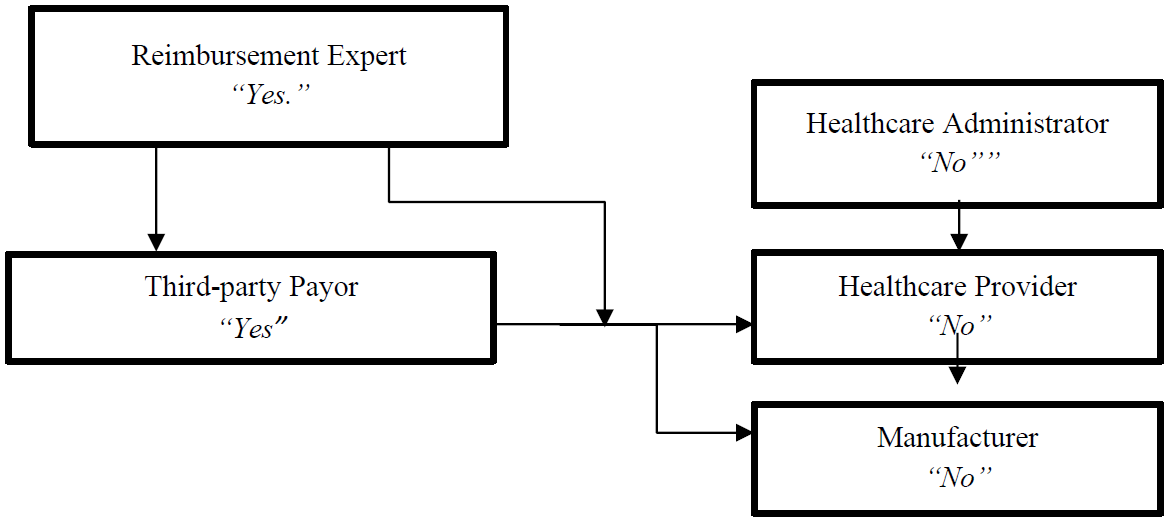

Figure 9. Responses to Survey Question 4

Question 5

Question 5: In your opinion, what are some factors, such as the type clinical evidence, that would be helpful, if any, for a commercial insurer to consider amending coverage CPT 92512?

The fifth question asked respondents their opinions related to the factors that would be helpful for a commercial and sure to consider amending the coverage of CPT 92512 such as clinical evidence. The commercial payor emphasized the importance of coverage and stated, "The most important item to support coverage is well-controlled prospective studies demonstrating that the results of nasal function studies alter clinical management such that clinical outcomes are improved." Upon further review of the citations and current literature in the literature review, studies are demonstrating this as evident in their results and conclusions; yet, CPT 92512 is considered experimental and investigational among two payors. The reimbursement expert gave a very detailed explanation of what could assist in amending the coverage of CPT 92512, by stating that the various levels of an experimental and investigational

treatment, authoritative evidence, and how these would affect evidence, yearly decisions would be helpful. The clinician agreed that the clinical evidence should be current and relevant, which would support the findings of the quantitative review, where many the citations in the CPBs were older and used in formulating policy coverage determinations. This finding supports the clinician opinion, stating that subject of policies should not use order information that may be misleading or out of indication. This is true, as innovation continues to be updated and brought to market through FDA approvals. The medical device industry looked at this question from a more global perspective by stating, "The mid- to long-term savings and successful solution of sleep disordered breathing, and which nasal obstruction is a part of sleep disordered breathing, via reduction of blood pressure, BMI, cardiac issues, stroke, and related comorbidities."

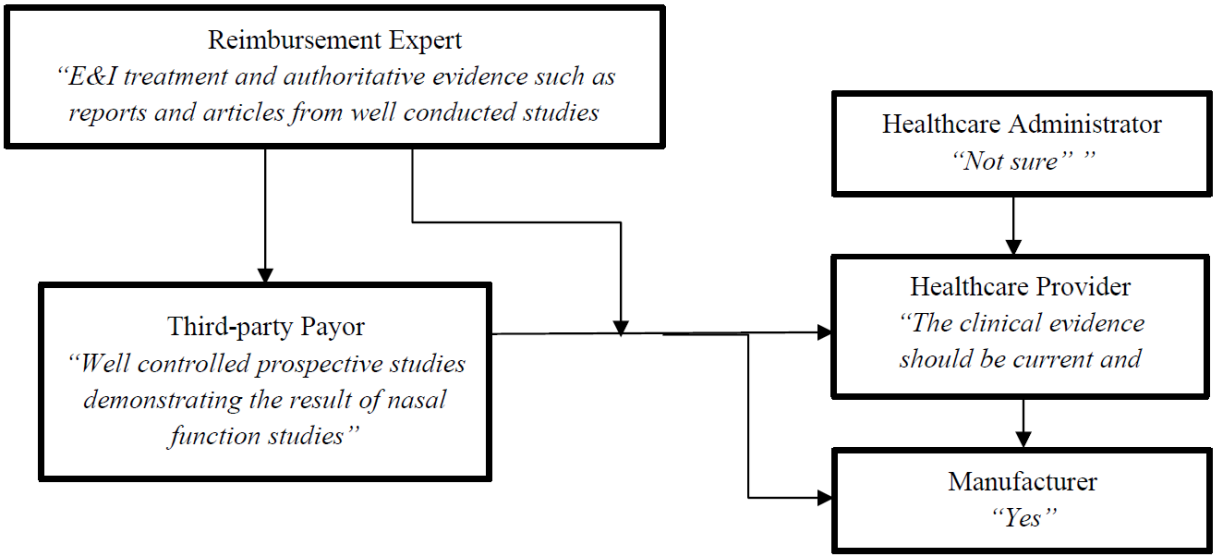

Figure 10. Responses to Survey Question 5

Question 6

Question 6: What do you like and what do you not like about the process of developing objective, clinically supported, and defensible coverage determination for CPT 92512?

When looking at the process of developing an objective, clinically supported and defensible coverage determination, we asked respondents in Question 6 what they liked or disliked about this particular process. The commercial payor stated,

> The process of developing objective, clinically supported and defensible coverage determinations have the potential to improve medical quality by supporting an evidence-based approach to medical care. The least appealing aspect is the lack of such data for many medical interventions that have been incorporated into clinical practice.

The reimbursement expert was not very clear on the direction of the question and did not have an opinion. The clinician was not sure of the process, but as a provider, did not like insurance companies telling them how to practice, hence, limiting them to technology and treating patients. They believed that objective data and information are very important in inpatient care. The healthcare administrator stated that without objective coverage, it does create a certain sense of chaos in the practice and can harm the relationship with them and the manufacturer, but limiting them access to the doctors and staff to educate and share new technology and innovation. The medical device and history agree with the opinion of the clinician and healthcare administrator, showing that interconnectedness of those on the end-user side of the experimental and investigational label by stating, “It would be any providers’ best interest to expand upon them in effect as pilot studies.”

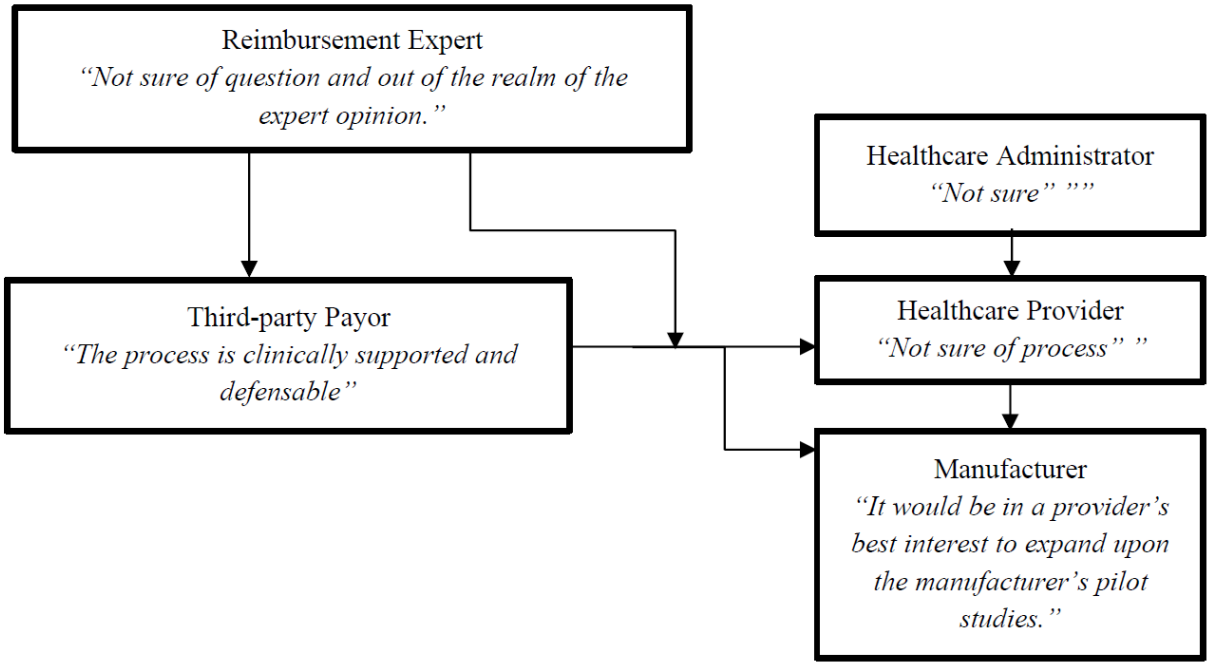

Figure 11. Responses to Survey Question 6

Question 7

Question 7: How do you think differences in the definition of clinical evidence, such as in the example of the FDA, influence the decision for coverage?

We asked the respondents what they thought about the differences in the definition of clinical evidence, such as the example of the FDA influences the decision for coverage. The purpose of this question was that there are several definitions of clinical evidence-based with organization, such as the FDA, CMS, and commercial payors (as found in the literature review). The answers varied amongst each group. The commercial payeos stated,

> FDA clearance of approval is necessary where required for marketing, but it may not be sufficient for coverage. In particular, 510(k) clearance requires the manufacturer to demonstrate substantial equivalence to a predicate device, but does not require submission of data demonstrating clinical utility.

The reimbursement expert stated,

> There are commonalities in how payers define clinical evidence and then there are additional sources of evidence that payers either require or will take into consideration. If working on a payer by payer basis it is important to understand their requirements for the type of clinical evidence they want. If looking at a national strategy you need to present not only the common criteria but include all the additional sources of evidence. I'm sending you some common sources of evidence payers typically will consider when reviewing technology.

The remaining three groups, the clinician, the CEO and the medical device industry, have very strong opinions, and stated,

> We see experimental and investigational differently as an FDA non-approved product, but anything approved by the FDA should be used for patients. I am not sure, but it appears that there are differences and the differences create subjective opinions about what will be a billable code. This determines how the providers practice and what the group is willing to spend on equipment and supplies. FDA officials are experts at ISO standards and not medical professionals. Insurance companies do a poor job of finding true experts as well since they look to academia. In western medicine, the best and brightest clinicians go into private practice while the lower tier graduates stay in academia.

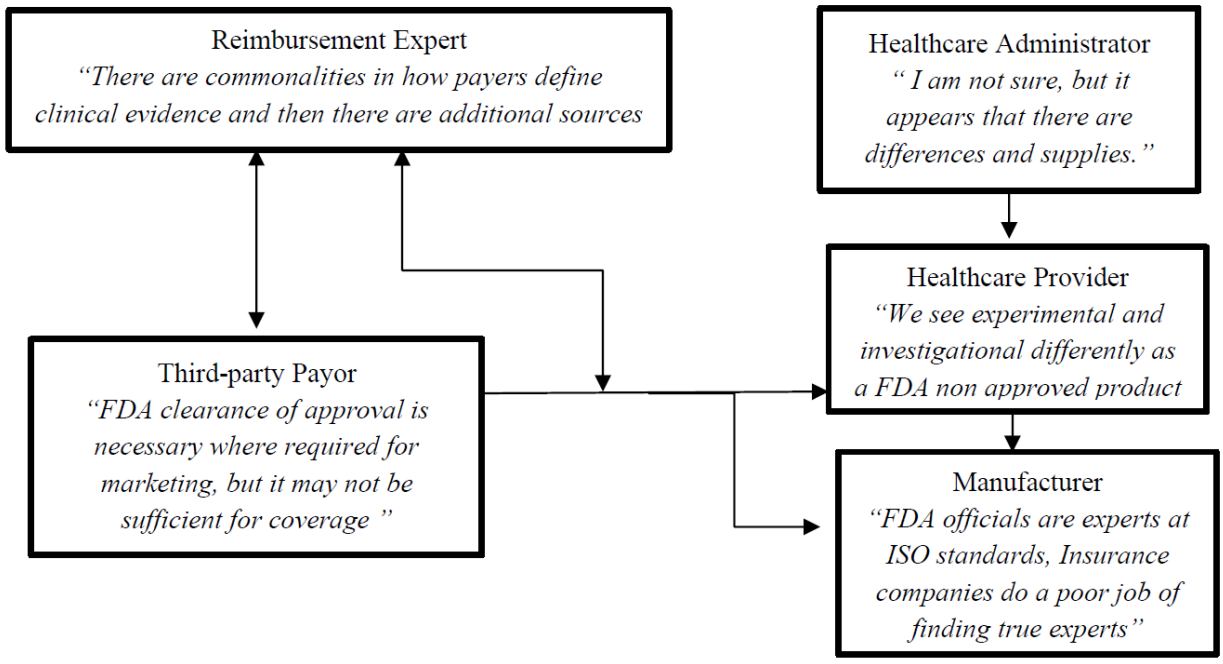

Figure 12. Responses to Survey Question 7

Question 8

Question 8: Does familiarity with the technology and instruments or the umbrella of products used under CPT 92512 influence the coverage decisions of third-party payors?

Question 8 looked at the familiarity of the technology and instruments or the umbrella of products used under CPT 92512, and how that influences the coverage decisions of third-party payors. It is of the universal opinion that when writing CPBs, or any healthcare policy, there should be a familiarity with the technology for which they are writing. The commercial payors stated, "We have medical director subject matter experts, including ear nose and throat specialists that can assist in familiarizing ourselves with the technology." The reimbursement expert stated,

> If there is educational information available that will help expedite the payors' learning process than it is worthwhile to provide the payer. Such information is typically the

preliminary step (to understand technology) to then began the review process. This piece, while helpful, is likely not to be a major influencer unless there is something very compelling to offer.

The clinician was not sure, neither was the healthcare administrator, but the medical device industry was very strong in their opinion, stating, "It would, but currently their lack of familiarity leads to the erroneous conclusion that measuring physiologic functions is "experimental" instead of common sense and a sound medical approach."

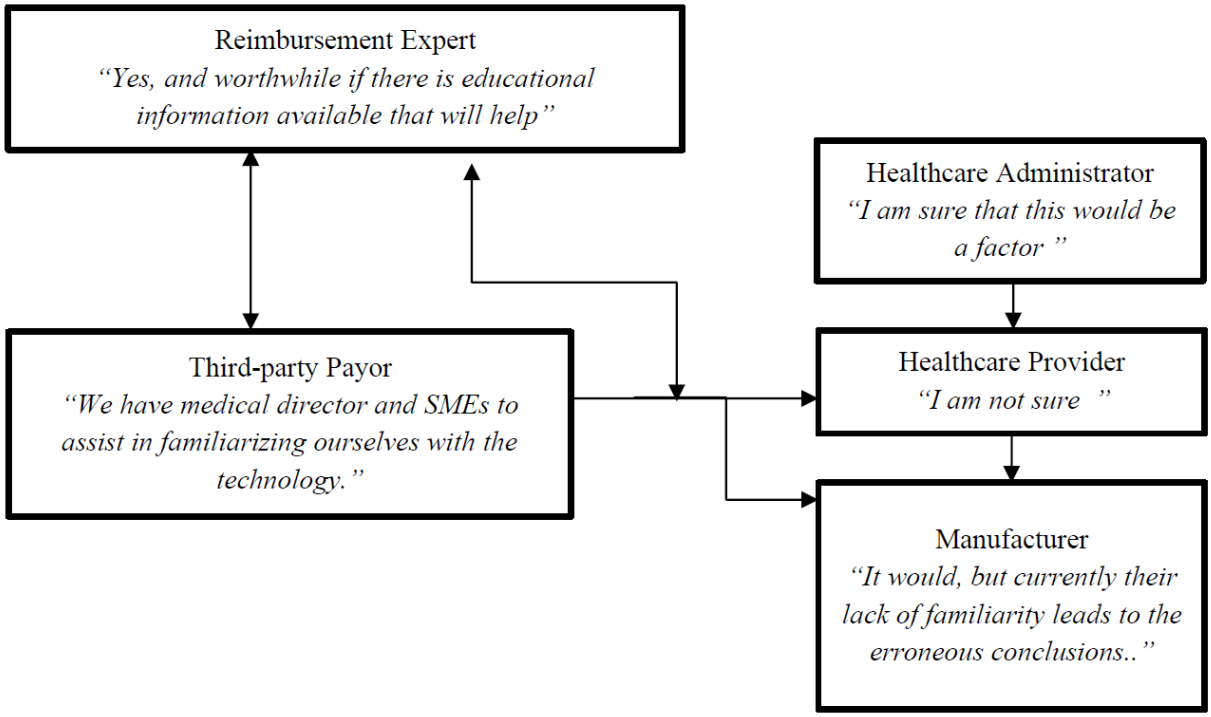

Figure 13. Responses to Survey Question 8

Question 9

Question 9: What do you think might be some of the aspects where the patients would benefit from coverage of CPT 92512?

In Question 9, we asked their thoughts about some of the aspects where the patient would benefit from the coverage of CPT 92512. The clinician and the medical device industry had a very strong opinion, by stating the necessity of the test for patient care,

> Avoiding unnecessary surgery when nasal breathing issues are easily treated such as in allergies. Treatment outcome measures to assess the best techniques for alleviating dysfunction. Allowing clinicians that treat pharyngeal airway issues to identify contributing or even primary nasal issues that if left unresolved, will leave patients with failed treatments that only address part of their problem.

By contrast, the commercial payor thought differently, by stating, "Nasal function studies have the potential to assist in decision-making regarding diagnosis and treatment of nasal congestion, polyps, and enlarged adenoids and for evaluating the impaired flow of nasal passages due to allergies, surgical procedures or medications." The reimbursement expert and the healthcare administrator did not have an opinion, due to a lack of knowledge or not enough information about the patient medical benefits to answer the question.

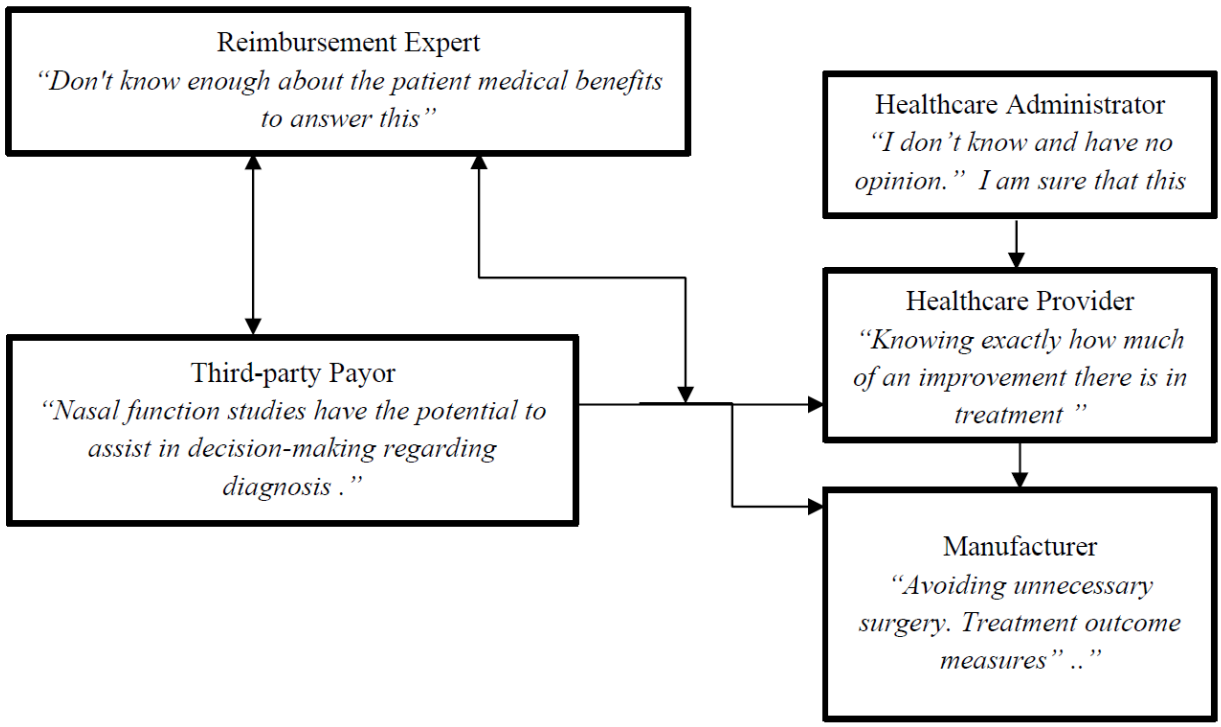

Figure 14. Responses to Survey Question 9

Question 10

Question 10: Do you know if there is the option of the patient or healthcare provider to appeal the decision of non-coverage?

As part of Question 10, when we asked asked about the option of the patient or healthcare provider in appealing the decision of non-coverage and if this was available to them, the respondents had similar responses and that the right to appeal is present and should be made available. Four groups had an overwhelming opinion of yes, the patient had the opportunity to appeal any decision, as do the providers, but the medical device industry did not know the option. The reimbursement expert appeared to have the most knowledge, stating,

> Patients can always appeal a denied claim. It is difficult to overturn claims on a case by case basis unless the provider can establish the detriment to the patient, the patient does

not have adequate medical information to determine a diagnosis or treatment plan, or where new clinical evidence is available to reconsider the claim.

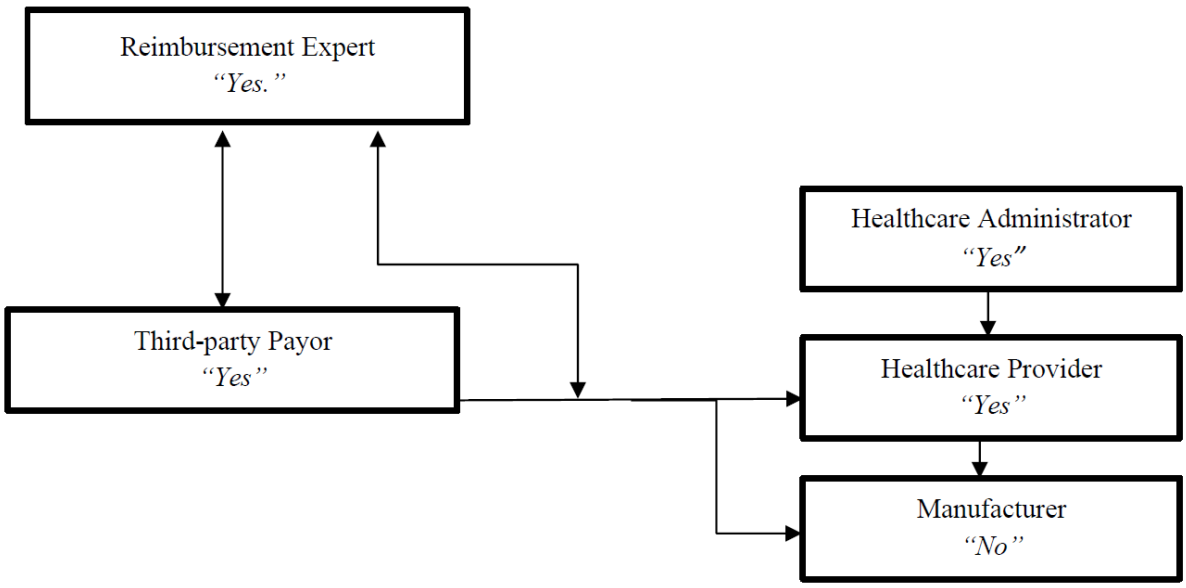

Figure 15. Responses to Survey Question 10

Question 11

Question 11: How often are appeals considered and approved by third-party payors? The decision of non-coverage?

Question 11 asked how often appeals are considered and if approved by third-party payors. The medical industry and the commercial payer did not have information based on the opinion of such information being proprietary; whereas, the reimbursement expert had the most knowledge, and as a valuable resource to all the groups stated, "As stated above overturning a denial in an appeal is difficult unless a good case can be made. If a compelling argument can be made the denial is often reversed." Additionally, the expert stated, "I cannot answer this question specific to CPT 92512. It does not appear that by not performing a nasal function test,

the patient would be subjected to medical risk … unless there is compelling information that I am not aware of."

The denial and appeal process can be difficult, but the clinician and the medical device industry did not know about the billing issues affecting the two groups' interconnection. The healthcare administrator was aware of appeals being filed and found them very time-consuming for the staff, so if non-coverage services are not used, it would not interfere with the workflow in the office. This is reflective of access to the manufactures to educate clinicians about new technology and innovation.

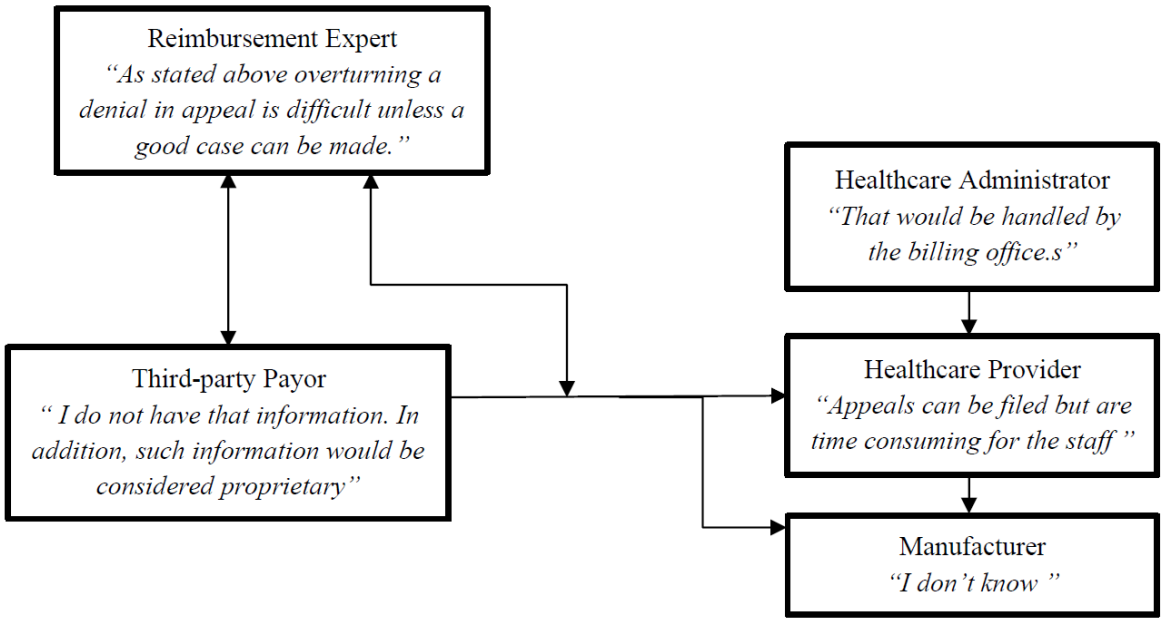

Figure 16. Responses to Survey Question 11

The theme of the respondents and their answers to the aforementioned questions is summarized in Table 15.

Table 15. The Theme of Qualitative Responses

Question	Commercial Payor	Reimbursement Expert	Healthcare Provider	Healthcare Administrator and CEO	Medical Device Industry
Aware of CPT 92512 coverage policy.	Yes	Minimal review	No	Not inclined to answer	Yes
Any risk or implication for not covering the test.	Neutral	Low risk	Yes	Yes	Massive risk.
Aware of historical information.	Designated rhinomanometry as unproven	No research was completed; therefore, not aware.	No	No	Yes
Knowledge policy review frequency.	Yes	Yes	No	No	No
Factors that would be helpful for the consideration of amending coverage.	Well-controlled prospective studies demonstrating the result of nasal function studies	E&I treatment and authoritative evidence such as reports and articles from well-conducted studies.	The clinical evidence should be current and relevant.	Not sure	Yes
Like and dislike about the process of developing coverage determination for CPT 92512?	The process pf developing objective clinically supported and defensible coverage has the patient to improve medical quality.	Not sure of what the question meant; this may be out the realm of the expert.	I am not sure of the process.	Without objective coverage, it creates a certain sense of chaos in the practice and can harm the relationship with device companies.	It would be in a provider's best interest to expand upon the manufacturer's pilot studies.
Differences in the definition of clinical evidence, influence the decision for coverage.	FDA clearance of approval is necessary where required for marketing, but it may not be sufficient for coverage.	There are commonalities in how payers define clinical evidence and then there are additional sources of evidence.	We see experimental and investigational differently as an FDA nor approved product.	I am not sure, but it appears that there are differences and supplies.	FDA officials are experts at ISO standards, Insurance companies do a poor job of finding true experts.
The familiarity of technology and influencing the coverage decisions of third-party.	We have medical directors and SMEs to assist in familiarizing ourselves with the technology.	Yes, and worthwhile if there is educational information available that will help.	I am not sure.	I am sure that this would be a factor.	It would, but currently, their lack of familiarity leads to erroneous conclusions.

Table 15. The Theme of Qualitative Responses (continued)

Aspects where the patients would benefit from coverage of CPT 92512?	Nasal function studies have the potential to assist in decision-making regarding diagnosis.	Don't know enough about the patient medical benefits to answer this	Knowing exactly how much of an improvement there is in treatment.	I don't know and have no opinion	Avoiding unnecessary surgery. Treatment outcome measures.
Option to appeal the decision of non-coverage?	Yes	Patients can always appeal a denied claim.	Yes	Yes	No
The frequency that appeals are considered and approved by third-party payors.	I do not have that information. Besides, such information would be considered proprietary.	As stated above overturning a denial in an appeal is difficult unless a good case can be made.	That would be handled by the billing office.	Appeals can be filed but are time-consuming for the staff.	I don't know.

CHAPTER V

DISCUSSION, LIMITATIONS, AND CONCLUSION

Discussion

The study looked at the factors associated with the label of experimental and investigational, specifically CPT 92512. The findings show third-party payors define experimental and investigational in a variety of ways; however, caution is needed in how these findings are generalized and interpreted in healthcare policy, reimbursement, and practice. Some payor policies provide the coverage determination as to the status of the proposed technology is to be made solely by the plan administrator, where other payors define experimental and investigational as those under the true definition of clinical investigation, those not deemed medically necessary and generally recognized by the medical profession as tested and accepted medical practice, or those still requiring approval by the FDA or other governmental agency. The content analysis of the CPBs revealed how some third-party payors establish corporate technology assessment committees with medical specialty members to determine what testing, therapies, and technology are covered under all of the policies issued by the healthcare insurer. By contrast, other plans exclude any coverage of testing, technology, or treatments that are provided in connection with medical treatment, other medical research, or research requiring the informed consent signature of patients. Ultimately, and by payor definition, coverage is determined by the benefit plan that will supersede the national plan and will vary from plan to plan. This limitation of coverage determination was imminent, as the research showed there are over 10,000 various healthcare plans in the United States.

According to the findings, the data illustrate this challenge by obtaining an understanding of the factors associated with the experimental and investigational label due to inconsistencies

among policy formation, policy information, understanding of the cited references, knowledge level of the technology when interpreting the outcomes of the study and incorporating them into a CPB, a break in the utilization flow of the knowledge of the CPT code and interconnectedness among the groups, and the lack of accessibility to view all policies. Therefore, the main drawback observed among all but a few studies cited in the CPBs was the number of cases, which was simply too small to determine the full spectrum of relationships among these parameters, outdated or incorrect information omitting the updates of the technology, and lack of updated consistent practice guidelines and statements. For the references to carry relevance in arguing the coverage determination of CPT 92512, larger numbers of cases in prospective, randomized studies are needed to determine relationships using CPT 92512 to adequately determine coverage parameters and policy. Without a large randomized study, the patient becomes the one lacking the appropriate testing and healthcare needed for optimal outcomes; therefore, more relevant and updated recommendations are needed for comprehensive policy formation, as in the example of the Pediatrics Allergy meeting in 2018 and Rhinology EAACI 2011 recommending rhinometry and rhinomanometry (see Table 11).

The CPBs within the content analysis stated within the policy that there was inadequate evidence of the clinical utility of rhinomanometry and acoustic rhinometry, and these tests have not been demonstrated to be superior to physical examination, nasal endoscopy, or computed tomography (CT) imaging in selecting patients who would benefit from medical and/or surgical management of their nasal obstruction. Clinical studies published in the peer-reviewed medical literature are necessary to determine the value of rhinomanometry and acoustic rhinometry in the diagnosis and clinical management of patients with nasal obstruction. One with extensive experience and in-depth knowledge of the technology would argue the results of a CPB based on

the evidence that the technology is not meant to be superior, but as an adjunct to determining the patient status preoperatively and outcomes post-operatively; no one technology is clinically tested or researched for superiority. Additionally, there are data to show a healthcare financial aspect of using the technology to test all patients and data that show the ability to determine candidates for surgery that would preclude about 20% from arduous surgery and side effects.

The review found that acoustic rhinometry has not only been used to examine hay fever patients, but in many different aspects of rhinology. Since the introduction of the acoustic reflection technique in the nose, more research using the technique have been published. Most of the research finds the technique valuable for the evaluation of nasal patency. Fortunately, some critical papers have drawn attention to some practical aspects of the technique. Standard operating procedures and calibration checks, as well as training operators, will enhance the accuracy and reproducibility of results. Many resources state the positive opinion of CPBs as recent as 2020, stating, "There is a need for objectivity in the testing of nasal patency arising from medicolegal, diagnostic and documentary purposes" (Bozdemir, Korkmaz, & Franzese, 2020, p. 20). Relevance to data within the policies found is attached to the UpToDate (2020), which describes itself as, "The only resource associated with improved patient outcomes and hospital performance, and studies show that clinicians who use UpToDate change their decisions 30 percent of the time" (para. 1). To further negate the label of experimental and investigational, the research found conclusively that the results suggest that the reliability of acoustic rhinometry (AR) appears sufficient for clinical and scientific use in the nasal cavities. References using the A1 Rhinometer are in favor of clinical application and usage, were references not mentioning A1 Rhinometer or NR6 Rhinomanometer had a controversial or negative view of objective nasal measurements.

Among the CPBs using the experimental and investigational label and in coordination of the findings among practice guidelines and practice recommendations, coverage for the CPT code will require the payors to consider the following in the policy of documentation requirements medical record documentation (e.g., history & physical, office/progress notes, procedure report, test results) must include the following information: (a) a complete medical and immunologic history and appropriate physical exam obtained by face-to-face contact with the patient; (b) the medical necessity for performing the test; (c) the test methodology used; (d) the measurement (in mm) of reaction sizes of both wheal and erythema response (in vivo testing); (e) the quantitative result (in kIU/L) for specific IgE testing (in vitro testing); (f) the interpretation of the test results and how the results of the test will be used in the patient's plan of care; (g) periodic clinical evaluation of treatment benefits and, if no benefit within 12-24 months, other treatment options which should be considered; (h) clinical re-evaluation at three to five years to determine the need for continuing immunotherapy.

Some have listed provocative testing (e.g., Rinkel test) as needing a certificate of medical necessity, and others will not cover it, stating experimental and investigational (Florida Blue, 2020; Wellmark, 2020). To reduce the liability of the experimental and investigational label, it appears that many will place a disclosure in the benefits application of the medical policy or clinical policy bulleting of the benefit application, stating that benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. The commercial payor determines medical necessity only if the benefit exists and no contract exclusions are applicable. The medical policy may not apply to a particular policy, and therefore, benefits are determined by the particular insurer program. The

medical policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. The medical policy also states that it will be reviewed regularly and be updated as scientific and medical literature becomes available.

The results found many counter-arguments existed as it relates to the standardized phraseology of the CPB that states, considers rhinomanometry, acoustic rhinometry, and optical rhinometry experimental and investigational because of a lack of clinical studies demonstrating that these tests improve clinical outcomes. For example, Schumacher (2004) reviewed rhinomanometry for nasal dyspnea and found that no other symptom of rhinitis can be measured as objectively and accurately as that of nasal obstruction. Schumacher determined that rhinomanometry is precise and meets the published requirements of standardization by the International Rhinologic Society. Furthermore, Schumacher (2004) found that rhinomanometry "has a proven place in the selection of patients for septal and nasal valve reconstruction" (p. 46).

Likewise, the research found both objective and subjective measure methods as important in evaluating nasal airway alterations from septorhinoplasty, since nasal complaints may be difficult to evaluate preoperatively and improvements postoperatively. Conclusively, the research found that acoustic rhinometry is non-invasive, repeatable, easily applicable, and very inexpensive. Acoustic rhinometry can "objectively evaluate and demonstrate surgical success by comparing preoperative and postoperative (septoplasty, polypectomy, turbinectomy, inferior meatal antrostomy, rhinoplasty, and anterior turbinoplasty) values using the section area and volume of the nasal cavity as a criterion." (Sakai, Marson, Sakuma, et al., 2016, p. 50). Acoustic rhinometry has an important role in making the diagnosis and particularly in the post-treatment follow-up.

The content analysis found that many policies referred to the evidence in the peer-reviewed medical literature, which can be defined as scientific studies printed in journals or other publications in which original manuscripts are published only after being critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. As an example, peer-reviewed medical literature does not include information from health-related websites or in-house publications of pharmaceutical manufacturers. In many of the cited references, the sample size of less than 25 was found, which in research, less than 25 participants in a study may affect the probability and statistical significance of an event occurring in a larger population.

With the increasing amount of research done in the medical community, an increasing number of findings and conclusions are contradictory, as in the case of many of the CPBs. Although there may be differences among polices that substantiate the observations of the research, the results may differ due to the sampling size. The sample size is relevant and important to readers of medical journals, because the relevance of the data is important to their patient population for care, and as in the case of commercial payors, the member population and the disease prevalence.

In the case of the cited references, the analysis showed a lack of justifiable levels for statistical significance and a targeted difference, creating variability in the data and conclusions; therefore, the CPB references assessed coverage based on the researchers presumed valid outcomes, measures, analyses, and conclusions claiming superiority or lack thereof of the technology and diagnostic testing used and the prognostics value of the testing, as in the case of rhinometry and rhinomanometry. The increasing paradoxical interpretation of the research findings creates confusion in the medical community and a sense of skepticism. This is evident in the CPB, and commercial payor opinion was written in their policies.

In addition to the significance of the study findings, the more variability of data, the more difficult it will be to differentiate between the treatments and the need for a larger sample. This would result in a study that is underpowered to the desired comparing efforts and lacking the probability of detecting a targeted difference that will decrease if it exists. Another consideration when reviewing the referenced citations for policy creation is the type and number of endpoints in the study. The endpoints and statistical tests used to influence the complexity of calculation and statistical finds, in essence, the larger the sample size, the greater the precision and correspondence with the confidence level and, therefore, a lack of power in detecting a meaningful difference.

The content analysis showed in another study, cited in the Aetna (2019) CPB 0700 policy, that many state the positive aspects of the technology, but do not mention the correlation for the need to use, even though the conclusions state the recommendations. Additionally, the policy is citing in the first paragraph of the abstract, "the correlation among these exams remains unclear"; however, this was the introduction of the study and problem statement, not the conclusion. The conclusion in the policy states, "There were correlations between acoustic rhinometry, computed rhinomanometry, and cone-beam computed tomography in mouth breathers with transverse maxillary deficiency" which would validate the need for coverage and eliminate the experimental and investigational label as found by Sakia et al. (2016, p. 50). It should be noted that 25 references were added to the policy since a review in October 2019, but not all were mentioned in the policy.

According to the findings, many journal reviews and discussions describe the various methods of objective measurements that can be used to measure nasal patency, airflow, and resistance, mainly peak nasal inspiratory flow (PNIF), rhinomanometry, and acoustic rhinometry,

but the CPBs do not mention PNIF. PNIF has been demonstrated to be a reproducible indication of objective nasal patency as formal rhinomanometry and has the advantages of being inexpensive, simple for patient use, suitable for serial measurements over time of treatment, and is especially convenient for home use across several populations from pediatric to adult. Just as in the lower airways, objective and subjective evaluation gives different information, which together optimizes the diagnosis and the treatment of patient. In 2016, many physicians continued to argue that PNIF should be used regularly in every outpatient clinic that treats patients with nasal obstruction. The following year, Hsu et al. (2017) found the mean VAS score, NOSE score, and the nasal resistance in the narrow side of the nose in the study group showed reduced symptoms at three, six, and 12 months postoperatively, compared with the respective preoperative measurements ($P < 0.001$, all), which contradicts the findings of a previous study in 2016 and part of the CPB citing uncertainty.

Additional research findings showed how inconsistencies in Velopharyngeal Insufficiency (VPI) were examined based on the citation in the CPB. The CPB stated that A1 and NR6 are experimental and investigational, but, Trindade et al. (2014) found acoustic rhinometry was able to identify, with good discriminatory power, the impairment of Velopharyngeal (VP) activity, which characterizes VPI. Likewise, Li, Wang, Chen, and Wu (2017) found good adaptability for VPI with A1. In other cases, two articles were reviewed from a database search of 11,439 articles from several databases. It is safe to presume that two articles are not a fair representation of a systematic review, yet the conclusions state-controlled studies attesting to the efficacy of measuring the geometry of nasal cavities for complementary diagnosis of respiratory mode are warranted (Melo et al., 2015).

Experimental or investigational means a service, supply, intervention, or drug that the plan has classified as experimental or investigational and, therefore, is not covered, even if the service, supply, intervention, or drug is considered medically necessary. The plan review consists of scientific evidence from well-designed clinical studies found in peer-reviewed medical literature, if available, and information obtained from the treating provider regarding the service, supply, intervention, or drug to determine if it is experimental or investigational. A service, supply, or drug not meeting all of the following criteria is, in the plan's judgment, investigational. Credible evidence is defined as,

> Only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating eligible provider or the protocol of another eligible provider providing or studying substantially the same drug, device, medical treatment or procedure; or the written informed consent used by the treating eligible provider or by another eligible provider providing or studying substantially the same drug, device, medical treatment or procedure" (BCBS of Kansas, 2005, para. 9).

The factor of credible evidence comes down to the subjective opinion of each payor, as defined in the policy and the interpretation of the data, which can be skewed to the outcome or result it is looking for, as in the case of medical polices and the interpretive coverage determination, without knowing the ire of the technology, financial aspects, or basis of the particular code. Additionally, not all medical devices are the same in reliability or sensitivity due to the evolving mire of innovation and improvements/enhancements, which should be taken into consideration. Upon review of many of the defining policies of experimental and investigational, many are dated in the early 2000s, which bares the questions of relevance and currency.

If interconnectedness was a factor in the experimental and investigational label, elimination of the label would improve, thus decedent the inner interconnectedness could be addressed without causing a ripple effect throughout the healthcare delivery system, causing less delay and setbacks for healthcare services and access to the technology. The benefits of interconnectedness among the five groups in reimbursement and policy lend credibility and accountability through the system, with improved efficiency for healthcare delivery by simply eliminating the experimental and investigational label.

Other factors associated with the experimental and investigational label and the cited references are the date of the cited references used to write the policy, the lack of newly updated data for consideration of coverage, the specialty in the citation, and the indication represented in the study. Many of the cited references in CPBs demonstrated the use of rhinometry and rhinomanometry as a tool to assist in the study, not as a tool in standard clinical practices.

Aetna

Aetna (2019) Policy 0700 states that rhinomanometry and acoustic rhinometry are experimental and investigational and therefore not covered. In support of the determination, the policy states,

> There is inadequate evidence of the clinical utility of rhinomanometry and acoustic rhinometry. These tests have not been demonstrated to be superior to physical examination, nasal endoscopy or computed tomography (CT) imaging in selecting patients who would benefit from medical and/or surgical management of their nasal obstruction. Clinical studies published in the peer-reviewed medical literature are necessary to determine the value of rhinomanometry and acoustic rhinometry in the

diagnosis and clinical management of patients with nasal obstruction (Aetna, 2019, para. 9).

The CPB demonstrates a variety of sources used to write the policy, and to date, this policy and rebuttals for coverage have been submitted in 2017 and 2018, without a determination or change in coverage; however, the review was completed with the industry rebuttal, as the rebuttal references were added to the citation list for the experimental and investigational label and updated policy in October 2019. The citations are those proving the need for and reliability of the test and that it does not determine outcomes, but rather assists in the diagnosis and success of procedures for optimal patient outcomes and improved quality of life. Respectfully, the CPB encompasses the action of subjectivity when writing policies, as many of the citations are foreign, outdates, or referring specialties and disease processes that are out of the realm of usage. For example, one citation refers to cystic fibrous. Based on the review of the policy, there appears to be a lack of understanding and knowledge of the technology on the part of the policy writers that the test is used often in research, and the research articles referenced are proving the outcomes of the disease using all tools of measurements for disease management, which rhinometry and rhinomanometry may or may not be used, as the case of cystic fibrosis.

This inconsistency creates a sense of chaos in healthcare delivery, policy, healthcare provider practice, and reimbursement. Furthermore, the authored citations state favorability of the technology in other articles, and possibly not the referenced research. This leads to inconsistently in the message and potential misinformation. The lack of knowledge or clinical article *cherry-picking* is evident by the verbiage in the policy, where the purpose of the study is stated and one line or phrase of negativity is stated as the reason or validation for the lack of coverage in the policy. As liability coverage to the experimental and investigational label, the

additional notes to the CPB, which if read carefully, can lead to additional coverage confusion for the patient, the provider, and the healthcare administrator.

In this CPB, Aetna's (2019) determination is detailed regarding whether certain services or supplies are medically necessary or if they are experimental, are under investigation, or are cosmetic:

> At Aetna, we reach these conclusions after reviewing the clinical information currently available (which includes studies of clinical results in the medical literature published and reviewed by professional peers; the regulatory status of technologies; evidence-based public health guidelines and of health research agencies; evidence-based guidelines and the position of leading national health professional organizations; opinions of doctors and dentists who practice in the relevant clinical areas; and other relevant factors). Aetna, we do not endorse or assume any responsibility concerning the content of the external information cited or referred to in this Bulletin. The exhibition, analysis, conclusions, and positions reflected in this Bulletin, including reference to a specific supplier, product, process, or service by name, trademark, or manufacturer, represent Aetna's opinion in this regard and are expressed without any intention to defame. In Aetna, we reserve the right to review these conclusions as the clinical information is modified and we accept all relevant additional information, including corrections of factual errors. Reference is made in Clinical Policy Bulletins to groups of standard codes that comply with the Health Insurance Portability and Accountability Act (HIPAA) to improve search functions and expedite billing and payment for covered services. New and revised codes are added to the Clinical Policy Bulletins as they are updated. At the time of billing, you must use the most appropriate code from the effective date of the presentation. Unregistered,

unspecified or unpublished codes should be avoided. For each benefit plan, which services are covered, which are excluded, and which are subject to limits in dollars or other types of limits are defined. Members and their providers should consult the member's benefit plan to determine whether exclusions or other benefit limits apply to this service or supply. *Although it was determined that a specific service or supply was medically necessary, that does not represent or guarantee that the service or supply is covered (for example, it does not mean that we will pay for it in Aetna) for a particular member.* Based on the member's benefit plan, the type of coverage is determined. Some plans do not include coverage for services or supplies that are considered medically necessary in Aetna. In case of discrepancies between this policy and a member's benefit plan, the benefit plan will prevail. Besides, certain legal requirements specific to a certain state, the federal government, or the Centers for Medicare and Medicaid Services may require coverage of Medicare and Medicaid members. You can find the coverage database of the Centers for Medicare and Medicaid Services at the following website: http://www.cms.hhs.gov/center/coverage.asp. (para. 1-8)

UnitedHealthcare Group

Bikhazi et al. (2014) evaluated and compared 1-year outcomes from the REMODEL study. Sinonasal symptom improvement was assessed using the validated 20-item SNOT-20 survey. Standardized effect sizes were computed to further assess clinical significance. Ostial patency rate, rhinosinusitis episode frequency, the impact of sinus disease on activity and work productivity using the validated Work Productivity and Activity Impairment survey, complications, and revision rate were also compared between the two groups. Ninety-two patients (50 balloon dilation; 42 FESS) were treated and 89 (96.7%) completed a 1-year follow-

up. Both groups showed clinically meaningful and statistically significant improvement in mean overall SNOT-20 scores and all four SNOT-20 subscales. The 1-year mean change in SNOT-20 after balloon dilation (-1.64) was non-inferior to FESS. The standardized effect size was large, showing clinically significant improvement for both interventions. Ostial patency was 96.7% and 98.7% after balloon dilation and FESS, respectively, and each group reported significant reductions in rhinosinusitis episodes (mean decrease, 4.2 for balloon dilation and 3.5 for FESS). Overall work productivity and daily activity impairment due to chronic sinusitis were significantly improved in both groups. There were no complications, and the revision surgery rate was 2% in each arm through one year. Bikhazi et al. concluded that with a 1-year follow-up, standalone balloon dilation is as effective as FESS in the treatment of CRS in patients with maxillary sinus disease, with or without the anterior ethmoid disease, who failed medical therapy and met the criteria for medically necessary FESS.

As for rhinometry in the role of the billing, procedure, and coverage, in a prospective, randomized, non-blinded, controlled trial, Bikhazi et al. (2014) evaluated and compared the clinical outcome of balloon sinuplasty and uncinectomy for patients suffering from isolated chronic rhinosinusitis of the maxillary sinus. The study included adult patients with symptomatic isolated chronic or recurrent rhinosinusitis without severe findings in the sinuses, as documented in the sinus' computer tomography scan and clinical examination, were randomized into two groups: uncinectomy and balloon sinuplasty. The variables in the study were the SNOT-22, acoustic rhinometry, and rhinomanometry. These parameters were analyzed preoperatively and postoperatively (after three and six months). Both balloon sinuplasty and uncinectomy significantly improved almost all the parameters of SNOT-22, with no significant difference found between these two groups. Based on rhinomanometry results, airway resistance

decreased after treatment. Regarding adverse effects, balloon sinuplasty was significantly associated with a lesser risk of synechia. Bikhazi et al. (2014) concluded that both balloon sinuplasty and uncinectomy improved the quality of life and decreased upper airway resistance of patients with mild, isolated chronic or recurrent rhinosinusitis. The procedure to clear the sinus opening is called a maxillary antrostomy. The procedure to clear the osteomeatal complex (OMC) is called an uncinectomy. The OMC is the collection of structures that aids in mucus drainage and airflow between the maxillary sinus, the anterior ethmoid air cells, and the frontal sinus.

Cigna

Cigna (2018) utilizes its own internally-developed coverage policies (medical necessity criteria) and the Milliman Care Guidelines when conducting medical necessity reviews of medical/surgical services, procedures, devices, equipment, imaging, and diagnostic interventions. Cigna's Coverage Policy Unit (CPU), in partnership with Cigna's Medical Technology Assessment Committee, conducts evidence-based assessments of the medical literature and other sources of information about the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies, and pharmaceuticals. The Medical Technology Assessment Committee's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence, as set forth in Cigna's Levels of Scientific Evidence Table, adapted from the Centre for Evidence-based Medicine, University of Oxford, and March 2009 (Cigna, 2018). The Medical Technology Assessment Committee establishes and maintains clinical guidelines and medical necessity criteria in the form of published coverage policies about the various medical and behavioral

health services, therapies, procedures, devices, technologies, and pharmaceuticals to be used for utilization.

BCBS of Alabama Experimental and Investigational Policy

Many of the BCBS companies act as independent licensees of the BCBS National Association. According to BCBS National Association (2019),

> medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment. (para. 4)

The policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in BCBS's administration of plan contracts.

> The plan does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment, or procedure is one made between the physician and his/her patient. The plan administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination. (para. 5)

As a general rule, benefits are payable under health plans only in cases of medical necessity, and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The Medical Policies Disclaimer for the Association Technology Evaluation Criteria (BCBS, 2018) must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting. (para. 4)

Medical necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient to prevent, evaluate, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. Per generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site, and duration and considered effective for the patient's illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and

4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease. (para. 4)

Experimental and Investigational from BCBS National Association

BCBS is the largest insurer of federal employees, covering nearly five million people. The policies contained in the FEP (Federal Employee Program) Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other healthcare professional in the treatment of an individual member. The BCBS National Association (2019) does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. The policy stated that medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their healthcare providers. The conclusion that particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Under the supplemental information clause, Practice Guidelines and Position Statements, and National Institute for Health and Care Excellence 2008 guidance on balloon catheter dilation of paranasal sinus ostia, the National Institute for Health and Care Excellence has stated: "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns." In 2016, the institute published a recommendation on the use of the XprESSMulti-Sinus Dilation System for the treatment of chronic rhinosinusitis 30:1.1:

> The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes, and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS). 1.2XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anesthesia. (BCBS National Association, 2018, para. 1)

In 2017, the American Academy of Otolaryngology-Head and Neck Surgery updated its statement on balloon ostial dilation, reaffirming its 2010 position statement:

> Sinus ostial dilation ... is a therapeutic option for a selected patient with chronic rhinosinusitis... This approach may be used alone ... or in conjunction with other instruments... , In 2015, the Academy's Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.32, American Rhinologic Society A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) ... who have failed appropriate medical therapy.", U.S. Preventive Services Task Force Recommendations Not applicable. Medicare National Coverage There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare. (BCBS National Association, 2018, p. 3)

Horizon BCBS New Jersey

> The policy considers Rhinomanometry and acoustic/optical rhinometry are considered *investigational.* Medicare Coverage under Horizon BCBS NJ (2019:1). There is no National NCD or LCD for jurisdiction JL for this service. Therefore, Medicare Advantage Products will follow the Horizon BCBSNJ Medical Policy (2019, para. 7-9). (NOTE: Overall, the scientific evidence does not permit conclusions about the effect of rhinomanometry, acoustic rhinometry, or optical rhinometry on net health outcomes. To date, no studies have been published that evaluate the clinical utility of these tests. That is, none of the studies identified have prospectively compared patient outcomes with and without the use of one or more of these tests for any clinical condition. Therefore, the technologies are considered investigational.)

As part of the review of references, this statement from Horizon BCBS (2019) demonstrates the lack of understanding of the products and potential lack of training by this statement:

> The results of the rhinometry test were classified into low-resistance (< 0.25) and high-resistance (> 0.25) groups before using decongestants, and high-resistance (> 0.18) and low-resistance (< 0.18) groups after use of decongestants. (3) (PDF) Assessment of Septoplasty Effectiveness using Acoustic Rhinometry and Rhinomanometry. (para. 6) This Horizon BCBSNJ Medical Policy (the "Medical Policy") has been developed by Horizon BCBSNJ's Medical Policy Committee (the "Committee") consistent with generally accepted standards of medical practice and reflects Horizon BCBSNJ's view of the subject health care services, supplies or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational. This Medical

> Policy also considers whether and to what degree the subject health care services, supplies, or procedures are clinically appropriate, in terms of type, frequency, extent, site, and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Medical Policy considers whether the subject health care services, supplies, or procedures are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the services, supplies, or procedures are more costly than an alternative service or sequence of services, supplies, or procedures that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical practice, the Committee reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty) and any other relevant factor as determined by applicable State and Federal laws and regulations (Horizon BCBSNJ, 2019, para 1).

BCBS Rhode Island

Rhinometry and rhinomanometry is defined as a procedure that is incorrect and defines acoustic and optical as the same, and they are not. Within the policy rhinomanometry and acoustic/optical rhinometry are considered not covered, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective. Commercial Products Rhinomanometry and acoustic/optical rhinometry are considered not medically

necessary, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective. BlueCHiP for Medicare and Commercial Products The following code 92512 is considered not medically necessary (BCBSRI, 2019).

Independence BCBS Experimental and Investigational Policy

The term experimental/investigational is used to describe services that address a drug, biological product, device, medical treatment, diagnostic test, or procedure that meets any of the following criteria (Independence Blue Cross, n.d., para. 7):

- Is the subject of ongoing Clinical Trials;
- Is the research, experimental, study, or investigational arm of an ongoing Clinical Trial(s) or is otherwise under a systematic, intensive investigation to determine its maximum tolerated dose, its toxicity, its safety, its effectiveness, or its effectiveness as compared with a standard means of treatment or diagnosis;
- Is not of proven benefit for the particular diagnosis or treatment of the Covered Person's particular condition;
- Is not generally recognized by the medical community, as clearly demonstrated by Reliable Evidence, as effective and appropriate for the diagnosis or treatment of the Covered Person's particular condition;
- It is generally recognized, based on Reliable Evidence, by the medical community, as a diagnostic or treatment intervention for which additional study regarding its safety and effectiveness for the diagnosis or treatment of the Covered Person's particular condition is recommended.

The analysis of the CPB found this is as completely subjective,

> The term Reliable Evidence is used to describe peer-reviewed reports of clinical studies that have been designed according to accepted scientific standards such that potential biases are minimized to the fullest extent, and generalizations may be made about safety and effectiveness of the technology outside of the research setting. Studies are to be published or accepted for publication in medical or scientific journals that meet nationally recognized requirements for scientific manuscripts and that are generally recognized by the relevant medical community as authoritative. Furthermore, evidence-based guidelines from respected professional organizations and governmental entities may be considered Reliable Evidence if generally accepted by the relevant medical community (Independence Blue Cross, n.d.a, para. 8).
>
> However, experimental/investigational is appropriate when used for Smell and Taste Dysfunction Testing Policy #: 07.11.01c, as it is not indicated for this type of pathology, and states (Independence Blue Cross, n.d.b, para. 30-33):
>
> Several diagnostic tests are considered experimental/investigational and, therefore, not covered when used in the diagnosis of smell/taste disorders including, but not limited to: a) Biopsy of the olfactory epithelium, b) Electrogustometry, c) Acoustic rhinometry, c) Rhinomanometry, d) Single-photon emission computed tomography (SPECT), and e) Positron emission tomography (PET) Functional magnetic resonance imaging (fMRI)
>
> Required Documentation: The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health

agencies, therapies, and test reports. The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial of the service.

Nasal measurements have been questioned or discredited on the premise of uncertain outcomes, reproducibility, lack of familiarity, and the importance in clinical practice, as the alternatives seem to be the status quo, sufficient, easy, or just a habitual behavior learned during residency and fellowship experiences. Many literature reviews and searches claim limited use for rhinometry and rhinomanometry, but fail to investigate the validity of patients' self-imposed subjective assessments on outcomes. In other policy writings, opinions and evaluations by national medical associations, consensus panels, and other technology evaluation bodies regarding their routine use are lacking; however, this remains contradictory to current society statements of practice. It has been recommended that objective measurements lack well in association with subjective measurements of nasal obstructions because the nasal valve area decides nasal resistance, while the esthesia of nasal blockage might be identified with congestion in other regions of the upper airway, for example, the ethmoid locale (Nathan et al., 2005).

Another conceivable clarification of the error amongst objective and subjective techniques for the estimation of nasal obstacle could be the absence of approved surveys and questionnaires. For the reliability of rhinometry and rhinomanometry procedures, CPT 92512, to be valid, they require sufficient training and control of the results, which appears to be missing in many of the citations of the CPBs, yet necessary in any experimental and investigational label consideration. The training deficiency is due in part to the regulatory absence of training by the manufacturer. Pirila and Tikanto (2006) best discussed the analogy with audiometry. To

achieve professional and reproducible results, the procedure should perhaps not be performed by doctors, who may do it only irregularly and in a hurry but by trained healthcare professionals who do the procedure on regular basis, and sufficient time must be available for the measurements

According to the research findings, the bias in peer review is another consideration when evaluating medical technology.

> There are 235 bias types, indeed, while up to 80% of research publications make little contribution to the advancement of science sitting in a wasteland of silence, attracting no attention whatsoever, it is disconcerting that the remaining 20% may suffer from bias as reflected in the increasing incidence of published studies that cannot be replicated or require corrections or retractions, the latter is a reflection of the power of the internet" (Landaw, 1983, p. 25).

Third-party payors determine the efficacy of technology on a short-term basis, but not the long-term basis in their peer reviews, hence calling it investigational.

The results showed that the financial health aspects of testing and using the technology were not mentioned or referred to in any of the CPBs, which should be considered when determining coverage. In the past, coverage was more prominent, chaotic reimbursement policies for healthcare providers and patients were less, and the number of surgeries was less. Healthcare economists acknowledged a growing consensus in the way physicians practice, their clinical decision making, and the role of healthcare decisions made by patients as having a lasting impact for many years.

The findings suggest the need for a review of clinical guidelines to reduce clinical costs should be a consideration and an element in the experimental and investigational label as a factor

for coverage determinations. Although the literature discussing guidelines and the consequences of cost is sparse, there is a financial saving to the healthcare system. Furthermore, this is reflective in the bias of healthcare policy because of the bias in citations and references used by third-party payors. It can only be assumed that clinical guidelines and statements of practice can reasonably reduce costs if they are considered in policy formation. The study shows very little consideration of reasonable consideration of the cost value based on well-established guidelines.

Although the terms experimental and investigational or medical necessity are those determined by a medical director or other policy origination teams, factors associated with the label and coverage determination could be related to being the requirement to diagnose or treat an illness, injury, disease or its symptoms; covered following generally accepted standards of medical practice; clinically appropriate in terms of type, frequency, extent, site, and duration for confirmation of diagnosis, not primarily for the convenience of the patient, physician, or other health care provider; and rendered in the least intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the policy team may compare the cost-effectiveness of alternative services, settings, or supplies when determining the least intensive setting or the risk of non-coverage to identify patient appropriateness for coverage.

The analysis of recent clinical studies and acoustic rhinometry showed a reasonable correlation with Computed Tomography (CT) in a cadaver and 10 subjects in comparison with MRI for the first 6 cm of the nasal cavity. Models based on MRI scanning of subjects also showed a good correlation for the first 6 cm of the nasal cavity. So, the debate continues, and the only reasonable soluton to the experimental and investigational label is to omit it from healthcare policy and reimbursement determinations.

In previous paragraphs, the research found the experiment and investigational label relevant and prominent in pharmaceuticals, with such phrasing and documentation in Coverage Requirements and Limitations with a categorization of access for patients and providers in the following type of script:

> To ensure that prescription drugs are used safely and cost-effectively, some drugs are included in our Responsible RX programs. These program requirements include a) Prior Authorization: Your doctor may need to submit a Prior Authorization request before the drug will be covered. Without Prior Authorization approval, your drug may not be covered and you may pay the full cost, b) Step Therapy: There may be another drug that is clinically effective that must be tried first. If you've already tried the other drug(s), your doctor can submit medical records for consideration, c) Quantity Limits: There may be a quantity limit on the amount filled each time. If you require more than the allowed limit, your doctor can submit a request for consideration. This should also be the same for testing with the label of experiential and investigational. (Florida Blue, 2020, para. 1-4)

Blanket policy statements on a subjective continuum of coverage determinations and denials of FDA approved products may be relative to the numbers of litigation cases for denial of coverage in healthcare law, when they could provide cost-savings to the commercial payor. Because of the profound health benefits of proper nasal breathing and cost savings uncovered in the study, it is in the financial best interest of the healthcare industry and commercial payors to make sure every possible necessary surgery is performed with screening using the CPT 92512 code, rhinometry and rhinomanometry, for high sensitivity and specificity of surgical necessity and for making the initial investment for proactive care. Because of the cost of surgery, it is in

the interest of the healthcare industry and commercial payors that every possible unnecessary surgery is avoided, resulting in millions of dollars in savings. Screening patients will give the healthcare industry and the ENT a clear idea of the potential for success of potential surgical cases an ongoing measurement of treatment outcomes.

Within several policies, and as noted by Horizon BCBSNJ (2019) Medical Policy, "There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL for this service. Therefore, Medicare Advantage Products will follow the Medical Policy" (para. 1) .

Upon further research, this commercial payor policy was inconsistent with the findings of the CMS policy analysis and was clarified by CMS. The NCDs and LCDs are developed by CMS and their carriers to describe the circumstances for Medicare coverage nationwide and locally for a specific medical service procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) and usually issued as a program instruction. One could argue that a nasal function study is not a device or procedure, but a test. Upon review of many NCDs looking at nasal obstruction, many were related to DME such as CPAP and oxygen therapy in the home. Even though each Medicare contractor has the discretion to establish which services are reasonable and necessary and therefore covered as a Medicare benefit, these coverage policies are issued in a document as most recently under the Palmetto-GBA LCD policy revision for Speech Pathology as of 01/01/2020, yet remains a non-covered code among many of the BCBS subsidiaries and Aetna. The CMS Outpatient Speech-Language Pathology, titled LCD Outpatient Speech-Language, LCD # L34429, Article titled Billing and Coding: Outpatient Speech-Language Pathology, Article # A56868 included

modifiers, ICD-10 Codes that Support Medical Necessity and HCPC?CPT codes, including CPT 92512. The policy states under Coverage Indications, Limitations and/or Medical Necessity

Speech-Language Pathology (SLP) services are defined as those services necessary for the diagnosis and treatment of speech, language, and cognitive-communication disorders which result in communication disabilities. Speech-Language quoted from the Centers for Medicare CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). Besides, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Under Section 6 of the policy, Nasal Function Studies is defined (CPT code 92512) Nasometry assessment is an instrumental assessment of resonance. This assessment provides numbers that represent a ratio between oral resonance and nasal resonance during the production of specific syllables, phrases, and reading passages. Normative data is available so that a patient's scores can be interpreted relative to normal. Nasometry helps quantify hypernasality and hyponasality. It also provides a baseline for measuring change following management-therapeutic or surgical. The speech-language pathologist performs clinical and instrumental assessments and analyzes and integrates the diagnostic information to determine candidacy for intervention as well as appropriate compensations and rehabilitate therapy techniques. The equipment that is used in the examination may be portable, mobile, or fixed.

From a clinical guideline perspective, many policies mentioned and referred to the AASM; however, the AASM policy for objective nasal measurements refers to the guideline and policy of the AMA. Again, this practice guideline was contradicting the CPB of Aetna, HCSC,

and BCBS in their statements for coverage. The most recent consensus statement came from an International Standardization Committee meeting on the Objective Assessment of the Nasal Airway in 2016. The conference aimed to address the existing nasal airway function tests and to take into account physical, mathematical, and technical correctness as a base of international standardization, as well as the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The committee concluded and agreed with Schusterman et al. (2019, para. 10) that for rhinomanometry, "The logarithmic effective resistance was set as the parameter of high diagnostic relevance, for rhinometry, "the area of interest for the minimal cross-sectional area will need further standardization", and for the PNIF, "peak nasal inspiratory flow is a reproducible and fast test, which showed a high range of mean values in different studies." The final directive from the consensus was that "the performance of an objective assessment of the nasal airway should not be underestimated as an element for a reliable relation, especially for the professional care in complex cases."

The ENT bears the cost of product purchase and application, so a reasonable fee needs to be paid for screening to ensure they follow the proper standard of care and not simply guess surgery will work. With CPT 92512 and screening being fast, non-invasive and affordable, the ENT can screen more patients, perform more necessary surgeries, and properly triage non-surgical cases to other treatment modalities and potentially decrease the ancillary costs of comorbid conditions and quality of life deficiencies resulting from disruptive or disruption in nasal function.

The research discovered a new trend of litigation, where law firms are specializing in denial of benefits cases for patients who want to take on commercial payors not willing to cover testing in an attempt of proactive healthcare among the public, which creates a breeding ground

for litigation in a tort free world, overprescribing of high technology such as CT and MRI, an environment of defensive medicine, and a contribution to higher healthcare costs. This could have a large implication on healthcare policy, to include higher costs to offset the defense costs of payors, especially without tort law limitations. The litigation industry is taking hold of the experimental and investigational label, as many firms are recruiting clients for litigation when claims involving FDA approved devices and technology is denied by a commercial payor based on the medical policy and benefit plan description. Under this language, treatments that are FDA approved and generally accepted in the medical profession as safe and effective should not be denied as investigational or experimental. In the case of *Boldon v. Humana Ins. Co.*, 466 F.Supp.2d 1199, 1212 (D. Ariz. 2006), the health plan's classification of cancer treatment as "investigational" was an abuse of discretion based in part on evidence of treatment's widespread use in cancer treatment centers across the United States. In another case, *Potter v. Blue Cross Blue Shield of Michigan*, No. 10-cv-14981, 2013 WL 4413310 (Mar. 30, 2013 E.D. Mich.), the ruling found that the medical literature established "long-term" efficacy of the treatment and should have been covered. This premise of payors, where health plans often deny such claims without thoroughly vetting the science behind the treatment, could be a factor associated with the detriments of the experimental and experimental label.

To examine the opinions of SMEs and the connection to the CPBs, CMS data, practice guidelines, and the factors associated with the experimental and investigational label, policy comparison and financial aspects of the policy should be considered to show how the responses are in line, or not in line, with the content analysis and literature review. The overall summarization of answers from the SMEs showed variation from the literature review and content analysis of the CPBs, yet agreement with CMS financial data and professional guidelines

and practice statements in support of a change in policy to eliminate the label and approve coverage, as all but two commercial payors presently support reimbursement.

Within the first two questions to the SMEs, the awareness of CPT 92512 coverage policy appears universal among the groups, so we know that there is a concern of policy determinations at some point in the reimbursement and revenue flow process of the healthcare system creating interconnectedness within the entire process. Furthermore, the administration of commercial payors' view of the neutral risk for not covering CPT 92512 is biased at best and lacks patient/provider consideration at worst. The manufacturer who completes market analysis and clinical trials for devices found massive risk based on the market feedback during the FDA approval process. The knowledge of CPT 92512 and value evaluation is important when bringing products to the market; however, the one constant is the commercial payor with their subjective policies and rebutted arguments from providers, administrators, and manufacturers.

The variation in payor policies, CMS NCD policies, and determinations show how a weighted opinion from the commercial payor, separate from the other groups outside of the insurer and those defined as the end-user, can alter the understanding and create unknown challenges. Many end-users are not aware of the changes and coverage determinations, creating a sense of chaos and practicing blindly, which can be elevated with policy change.

The third question identifies this strong, secluded, and isolated understanding of the historical policy review to the payor, but does not appear to share the information with end-users or administration, as evident by the responses. Without the historical information/data to confirm and support previous coverage of CPT 92512 before the current decision of non-coverage and policy review changes, as listed in the CPB, the sense of ambiguity is further escalated, causing providers to practice blindly and administrators to divert access to them by the

manufacturers. Due to the nature of reimbursement, the reimbursement expert is knowledgeable of most policy changes and aspects of coverage to assist end-users, but not all data across the board.

Factors that would be helpful for the consideration of amending coverage identified by the commercial payor were well-controlled prospective studies demonstrating the result of nasal function studies, yet there was lack of specific and extensive evidence labeling the experimental and investigational treatment and authoritative evidence, such as reports and articles from well-conducted studies. By contrast the studies considered valuable and accepted by commercial payors lack the clinical evidence, as viewed by groups outside of the insurers who argue the need for currency and relevance. Among the factors for amending coverage, the financial aspects of non-coverage are not mentioned, but should be, as this could persuade the decision of the commerce payor and policy.

The research found a juxtaposition of opinion and lack of cohesiveness of the commercial payor's opinion beyond the value of CPT 92512 and the likes and dislikes about the process of developing coverage determination for the code. The commercial payor sees the need for well-controlled studies, yet views the process of developing objective, clinically supported and defensible coverage has the need to improve medical quality and the patient is the focus. The administrative group says it is not sure of what the question meant; this may be out the realm of the expert, but there is an observation that without objective coverage, it creates a certain sense of chaos in the practice and can harm the relationship with the device companies. According to the opinion of the manufacturer, the maker of any medical product, and the value it has, it would be in a provider's best interest for the commercial payor to expand upon the manufacturer's pilot

studies and consider accepting practice guidelines as they are and not interpreted by one or more sentences, as we saw in all the CPBs that tout the experimental and investigational label.

Furthermore, the research found reimbursement experts express the same inconsistencies in factors that define experimental and investigational continue a presence, when all but two commercial payors did not see differences in the definition of clinical evidence influencing the decision for coverage and agree along the lines of FDA approval guidelines for use; however, two of the largest payors agree that FDA clearance of approval is necessary where required for marketing, but do not agree to state it may not be sufficient for coverage from one of the groups in the interviews. The literature review showed that there are commonalities in how payors define clinical evidence, and then there are additional sources of evidence. Commercial payors see experimental and investigational differently as non-FDA approved products. FDA officials are experts at ISO standards, and many manufacturers recognize the inconsistencies in the experimental and investigational definition, with the opinion that insurance companies do a poor job of finding true experts. This may be more evident in the findings of this study and future studies examining the experimental and investigational policies and reimbursement determination.

Although policy inconsistencies and differences do not mean a negative outcome, the familiarity of technology and influencing the coverage decisions of third-party for CPT 92512 is necessary for understanding the value and need for the technology, especially as it is updated and revised for changes in delivery, as in the case of software and electronic medical records affecting the experimental and investigations label. The study found tendencies in inconsistent policy from the content analysis and as answered among the groups. The commercial payor stated that even with the medical director and SMEs to assist in familiarizing them with the

technology, they may not have the most up-to-date information, as evident by the funding of the CMS data and CPB content analysis. Yes, it is worthwhile if there is educational information available that will help, but the healthcare providers are not sure that this would be a factor. The healthcare providers are correct, as many attempts to educate the commercial payor with an onsite demonstration are declined and overlooked, as stated by manufacturers. We found it necessary, but currently, the commercial payors' lack of familiarity leads to erroneous conclusions.

The inconsistencies from commercial payors when considering the aspects where the patients would benefit from coverage of CPT 92512 continue to fall out of the line of the perspectives found in the literature and other evidence found from the research. The commercial payor stated that nasal function studies have the potential to assist in decision-making regarding diagnosis, yet stray from the claim of clinical evidence needed, but state it is not present in the coverage policies. The administrative arm of the groups did not know enough about the patient medical benefits or had no opinion to answer these questions, knowing exactly how much of an improvement there is in treatment. In a continued pattern of agreement from the clinical arm of the group, which consisted of providers and manufacturers, and with the payors covering CPT 92512, many will claim that avoiding unnecessary surgery and measuring treatment outcomes are essential for quality healthcare delivery. The agreement of coverage is substantiated from the CMS financial aspects of reimbursement data and in identifying the 20% of patients who are not good candidates for healthcare savings.

The last questions showed a slight manipulation in care based on the option to appeal the decision of non-coverage. It should be noted that the elimination of the experimental and investigational label would negate the need to appeal a coverage decision. The consensus of all

groups is that of agreement and demonstrates the interconnectedness of viewing the patient first; however, the frequency that appeals are considered and approved by third-party payors still occurs and creates a loose scenario for the patient. Furthermore, it creates a social injustice of the haves versus the have nots and their access to innovation and technology. Regardless, the information from commercial payors remains proprietary. As stated, overturning a denial in the appeal is difficult and time consuming for the staff, unless a good case can be made.

To summarize the qualitative portion of the study is to essentially qualify the actions of commercial payors and the iron fist they carry over the healthcare system and policy, even when the data found otherwise. These actions further implicate healthcare policy change and require recommendations to equalize the substantial difference of the experimental and investigational label definition and coverage policies for a particular device and technology.

Limitations

Limitations to the study include access to medical policy terms, coverage economics of the experimental and investigational label, and EOBs from commercial payors, as the data are deemed proprietary and not available to the public; a more broad view of policy standards due to the number of member plans on the market; and the limited amount of studies looking at the interconnectedness of parties within the healthcare system. This topic requires further research for improved policy and healthcare delivery. The number of interviews, placed as a case study, was small and could have been more reflective with a larger number of SMEs from commercial payors. There is a need for further research, as the findings were based on a rather limited number of payors' opinions and processes, but a large number of CPBs for content analysis. This is a snapshot of the perceptions of one representative of the market, and the decision was to study the views of one representative of each group.

Policy Implementation and Changes

According to the findings, much of the healthcare delivery options for patients and the driving forces of the healthcare market are driven by one factor, the inconsistent lack of governance and contradictory, subjective opinions of CPBs for CPT 92512 among commercial payors. All but two insurers' CPBs and coverage policies fall in line with the content analysis, the qualitative data, and how the FDA and CMS quantify and qualify the use of products and innovative technology. The clinical evidence or evidence-based medicine presented in the literature review shows the lengthy history and value of CPT 92512; however, a few payors and their subsidiaries will overlook these data, even though it is stated as consideration for coverage. Furthermore, the use of the products and technology under CPT 92512 is validated with overall cost savings, CMS national utilization, and national reimbursement data beyond the payors' experimental and investigational label and lack of financial savings for omitting coverage. This is representative of the difficulty to make changes, even when the evidence is strong and historical.

The research findings show the increased awareness of CPT 92512 from the amount of CMS data, the number of insurers who have CPBs and experimental and investigational policies within the content analysis, and the opinions of SMEs, yet create a policy failure. Policy failure is simply the amount of information that goes adrift within the continuity of care among insurers in the interconnected systems of healthcare delivery, not a failure of the insurer or provider. This appears to be one of the key factors associated with the experimental and investigational label. It is important for the factors, or lack thereof, associated with the label of experimental and investigational and coverage determinations among all payors to be consistent from a federal definition of experimental and investigation label and supersede individual coverage

determinations to avoid the altered understanding of health policy, while creating unknown challenges among all parties in the interconnected system of healthcare. The research found that many end-users are not aware of the changes, the number of reviews, the experimental and investigational definition, or the coverage determinations of third-party payors, creating a sense of chaos and practice liability. Likewise, the coverage determinations dictate practice standards outside the professional opinions and guidelines that could be viewed as a negligent view of payors monitoring the practice of medicine and enhancing the injustices of healthcare delivery to patients. It is important to have a familiarity with third-party payor clinical policies to avoid an action that leads to the erroneous conclusions of claim denials and negative coverage decision consequences. For this to deviate from broad messaging and dispersed governance, political and administrative models are needed for regulation and performance management.

This was the first study of its kind to examine CPBs and the factors associated with the experimental and investigational label of a particular CPT code with consideration of practice guidelines, opinions of SMEs, and the economic analyses exhibiting the financial impact, savings, and budget neutrality. Even in light of this being a multidimensional problem, policy implications require continuity and transparency among all payors, with a current majority coverage rule, as on the case of most payors reimbursement for CPT 92512. The resolution of the problem should be elevated to the highest level, with policy change to eliminate the experimental and investigational label of FDA approved products at the level of governance from the HHS within the implications of the findings in this study.

Conclusion

Throughout this content analysis and qualitative study to understand the reasons why some of the experimental and investigational medical procedures are not covered by payors, this

continues to be a multidimensional problem, which often relies on the subjective interpretation of evidence by many payors. Furthermore, the effects in the power of coverage policies remain complex and decentralized in a systemic pattern of coverage determinations. This power plays an important role in healthcare delivery and utilization of FDA approved innovation and billing for coverage determinations. The criteria and factors associated with the label of experimental and investigational, and coverage determination factors of FDA approved products when writing clinical policies for reimbursement is not precise, as the subjective opinions are without a unified message and algorithm for coverage that fail the practitioner and patient, at best. Coverage policies inconsistently affect utilization and should be changed, especially when caution is needed in how the findings in CPBs are generalized and interpreted in healthcare policy, reimbursement, and practice.

Coverage policies offer an alternative means of controlling healthcare expenditures with testing and patient identification for surgical procedures, yet the experimental and investigational label determines what innovation and testing will be used by providers. The financial aspects of each experimental and investigational label are of paramount importance, even without a solid conceptual framework to justify the lack of coverage; however, a simple value analysis would be prudent. Conclusively, the healthcare calculations showed how the ability to determine candidates for surgery would preclude about 20% of patients from arduous surgery and postoperative side effects while offering a return on investment (ROI) to the payor of 6:1.

While private payors do not have to follow the rules set forth by the federal government and CMS, many find the CPT coding system for coverage and reimbursement as a well-established and familiar system. Here is the discrepancy, many polices elude the lack of governance between a the experimental and investigational definition, the medical policy, a

member's benefit plan, summary plan description, or contract, and the benefit plan where the summary plan description or contract will govern. It alters patient care delivery out of subjectivity, not to mention the economics of the label, lack of coverage, the quality of life, and the social injustices of patients.

The analysis outcomes and results are to create change in policy by presenting the findings to third party payors and congressional members for change in healthcare policy by eliminating the label of experimental and investigational when covering/reimbursing for FDA approved innovation and testing. Without the partnership of insurers, providers, and manufacturers, healthcare policy and reimbursement will remain in a stalemate abys in a lose-lose situation, with the patient on the receiving end.

There are several regulatory implications of the experimental and investigational label, even with the current healthcare policy changes of coverage for preexisting conditions. Still, the factors associated with the label and coverage of CPT 92512 supersedes the acceptance of preexisting coverage as a matter of policy law, noted in the Affordable Care Act, and recently supported by President Trump. The elimination of the label will create more consistent healthcare delivery, less administrative chaos in a physician practice, and address social justice equality in healthcare delivery with access for all patients. The research of one CPT code emphasizes a need to create a broader standardization in coverage policies to undo the social injustices of healthcare delivery and policy; yet, having third-party payors considering manufacturers' positions for coverage, prevents the practice of defensive medicine and omits any potential of fraudulent billing and reimbursement.

One thing is constant, the research included evidentiary use of CPT 92512 without factors associated with the label of experimental and investigational through 19 years of CMS claims

data, professional guidelines, current and historical standards of practice, professional society recommendations for the use of nasal function studies and objective airway measurements in clinical practice, written policy opinions and guidelines on the use and coverage and reimbursement of CPT 92512, nasal function study, yet allowing commercial payors to determine the eligibility of reimbursement for the code. Furthermore, if commercial payors continue to determine the eligibility of coverage for FDA approved products with the experimental and investigational label, they will continue to possess the power of affecting innovation, the certainty of diagnoses and care, and technology use beyond their historically few negative determinations of coverage and CPBs. The more restrictive policies represent a departure from the gold standards of Medicare by limiting innovation and technology, the healthcare providers' obligation to provide the best care, and the patient's right to obtain a full range of medical testing and treatment.

APPENDICES

APPENDIX A

SUBJECT MATTER EXPERT QUESTIONS

As part of the qualitative portion of the research, your opinion(s) and insight about the factors and criteria associated with the label of experimental and investigational as it relates to CPT 92512, nasal function study, will be added to the research to better understand the Experimental and Investigational (E&I) label. Acoustic rhinometry is a diagnostic measurement of cross-sectional area and length of the nose and the nasal cavity through acoustic reflections. It can be used to measure nasal anatomical landmarks and physical nasal airway changes. Rhinomanometry is a standard diagnostic tool aiming to objectively evaluate the respiratory function of the nose. It measures pressure and flows during normal inspiration and expiration through the nose. Questions to be asked of the SMEs:

1. Are you aware of CPT 92512 and coverage in reimbursement policy for any insurer, and is it covered? Why, or why not?

2. In your opinion, is there a risk or implication of not covering the code for the test? What would that be?

3. Are you aware of historical information/data to confirm and support previous coverage of CPT 92512 before the current decision of non-coverage? If so, what, in your opinion, may have changed the policy?

4. When you received the invitation for the interview, were you aware of how often a/the policy is reviewed? If, so, how often?

5. In your opinion, what are some factors, such as the type of clinical evidence that would be helpful, if any, for a commercial insurer to consider amending coverage CPT 92512?

6. What do you like and what do you not like about the process of developing objective, clinically supported, and defensible coverage determination for CPT 92512?

7. How do you think differences in the definition of clinical evidence, such as in the example of FDA, influence the decision for coverage?

8. Does familiarity with the technology and instruments or the umbrella of products used under CPT 92512 influence the coverage decisions of third-party payors?

9. What do you think might be some of the aspects where the patients would benefit from coverage of CPT 92512?

10. Do you know if there the option of the patient or healthcare provider to appeal the decision of non-coverage?

11. How often are appeals considered and approved by third-party payors?

APPENDIX B

CASP SYSTEM REVIEW OF CPBs

1. Did the review address a focused group? For example, the population studied, the intervention given, the outcome considered.

2. Did the authors look for the right type of papers? For example, did they address the review's question have an appropriate study design?

3. Do you think all the important, relevant studies were included? Which bibliographic databases were reused follow up from reference lists, personal contact with experts, unpublished as well as published studies, non-English language.

4. Did the review's authors do enough to assess the quality of the included studies? The authors need to consider the rigor of the studies they have identified. Lack of rigor may affect the studies' results ("All that glitters is not gold).

5. If the results of the review have been combined, was it reasonable to do so? Consider whether results were similar from study to study, results of all the included studies are displayed, results of different studies are similar, and if reasons for any variations in results are discussed.

6. What are the overall results of the review? If you are clear about the review's "bottom line'.

7. How precise are the results? Look at the confidence intervals, if given.

8. Can the results be applied to the local population? Consider whether the patients covered by the review could be sufficiently different from your population to cause concern and if your local setting is likely to differ much from that of the review.

9. Were all important outcomes considered? Consider whether there is other information you would like to have seen.

10. Are the benefits worth the harms and costs?

APPENDIX C

UNITED HEALTHCARE COVERAGE POLCY

This Medical Policy assists in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice. This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5). UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare. Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice."

APPENDIX D

AETNA POLICY FOR EXPERIMENTAL AND INVESTIGATIONAL

Coverage of Experimental and Investigational Procedures Policy Aetna covers experimental or investigational technologies (i.e., drugs, procedures, and devices) when ALL of the following criteria are met.

1. The member has a current diagnosis that will most likely cause death within one year or less despite therapy with currently accepted treatment; and
2. Standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and
3. The proposed treatment is likely to be beneficial to the member based on at least two documents of medical and scientific evidence (as defined below); and
4. The member is to be treated as part of a clinical trial satisfying ALL of the following criteria:
    a. The investigational drug, device, therapy or procedure is under current review by the FDA and has an Investigational New Drug (IND) number
    b. The clinical trial has passed independent scientific scrutiny and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation
    c. The clinical trial is sponsored by the National Cancer Institute (NCI) or similar national cooperative body (e.g., Department of Defense, VA Affairs) and conforms to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials; and
    d. The clinical trial is not a single institution or investigator study (NCI-designated Comprehensive Cancer Center trials are exempt from this requirement)
5. The member must:
    Not be treated "off protocol", actually be enrolled in the trial. Note: Some investigational studies are not conducted under FDA scrutiny, but meet all the other criteria. For example, new uses of old technologies, new uses of drugs already approved by the FDA (as these would not have an IND number).
6. Medical and scientific evidence means the following sources:
    a**.** Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
    b**.** Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR).
    c. Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x).

d. The following standard reference compendia: The American Hospital Formulary Service-Drug Information, The American Medical Association Drug Evaluations, The American Dental Association Accepted Dental Therapeutics, and The United States Pharmacopoeia Drug Information.
e. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the: Federal Agency for Healthcare Research and Quality, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Centers for Medicare and Medicaid Services (CMS). Any national board recognized by the National Institutes of Health forth purpose of evaluating the medical value of health services.
f. Peer-reviewed abstracts accepted for presentation at major medical association meetings. If the criteria listed above are not satisfied, and the member desires reconsideration, the member may submit an appeal in accordance with the relevant appeal process. Any such appeal may be expedited when required by the member's medical condition.

Note: For coverage of Category Investigational devices, please see CPB #164 — Coverage of Category Investigational Devices. See also CPB #466 — Clinical Trials, Coverage of Routine Patient Care Costs.13.03.313.1-NY (11/04). Application to products Unless indicated otherwise above, this policy applies to all fully insured Aetna HMO, Posed PPO plans, and to all other plans, unless specific limitation or exception exists. For self-funded plans, consult individual plan sponsor benefit descriptions. If there is a discrepancy between this policy and a self-funded customer's plan of benefits, the provisions of the benefits plan will govern. Concerning fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans, applicable state mandates will take precedence over either. Texas-specific coverage issues can be found on the following Aetna website:www.aetna.com/cpb/ data/texas_lang.htm Unless otherwise specifically excluded, Federal mandates will apply to all plans. Concerning individuals covered under aMedicare+Choice and state Medicaid benefit plan issued, serviced, or administered by Aetna, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Coverage Policy Bulletin. CMS's Coverage Issues Manual can be found on the following website www.hcfa.gov/pubforms/06_cim/ci00.htm (Aetna, 2002).

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