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Documenting Pharmacogenomic Testing with Current Procedure Terminology (CPT) Codes, A Review of Past and Present Practices

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Abstract

Pharmacogenomics is the study of how genetics can impact drug response and it aims to maximize therapeutic efficacy while minimizing adverse drug effects in individual patients. The current push for "personalized" approaches to medicine has brought pharmacogenomics to the attention of the healthcare community and the general public. It has been established that the efficacy or safety of certain drugs is impacted in part by the presence of genetic variants and/or other biochemical factors, which may contribute to variable drug response. Consequently, pharmacogenetic testing has been recommended by the FDA to guide the therapy with certain drugs in specific therapeutic settings. As the utilization of pharmacogenetic tests become more ubiquitous in healthcare, there will be a greater need to understand how to document these tests using current procedural terminology (CPT®) codes for the purposes of billing, reimbursement, and recordkeeping. Prior to 2012, most pharmacogenomic tests were considered "molecular pathology" procedures and documented as such. This practice resulted in non-specific documentation that often did not accurately reflect the actual tests performed. The American Medical Association addressed this problem in 2012 and new CPT codes were created to allow for easier, more specific documentation of pharmacogenomic tests. The goal of this article is to provide insight on the status of pharmacogenomic testing, as well as to highlight examples of current CPT codes for tests recommended by the FDA or drug manufacturers to assist in drug therapy. As the utilization of pharmacogenomic testing becomes more widespread, knowledge of how to document these tests will become more valuable.

INTRODUCTION

A wealth of new data concerning how human genetic variation contributes to drug response has the potential to change the practice of medicine. The "personalized medicine" paradigm is at the forefront of discussions about the future of healthcare. The promise of treating patients based on their individual characteristics, rather than by using empirical and generalized guidelines, interests many in the healthcare and scientific communities. The

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DECLARATION OF INTEREST

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individualization of drug therapy by using a patient's unique genetic make-up has already been implemented into practice. In parallel, the pharmaceutical industry has been developing a growing armamentarium of new drugs that are effective in specific subsets of patients carrying distinctive molecular signatures. Pharmacogenomics, which is the study of how genetics impact drug response, aims to develop patient-specific strategies for drug therapy by combining concepts from various disciplines including pharmacology, pharmacokinetics, drug metabolism, genetics, pathology, and pharmacodynamics (Kitzmiller et al. 2011). Pharmacogenetic tests allow clinicians to better predict the potential efficacy or toxicity of a drug in a particular patient. These tests can detect the presence of a specific genetic variant in a patient's DNA, a particular mutation in tumor DNA, combinations of mRNA transcripts in tumor samples, or the expression of specific proteins in tissue specimens. All of the aforementioned factors have the potential to impact drug therapy. Pharmacogenomic testing can be performed before or during therapy, and in some cases it allows for more precise treatments of diseases, such as certain types of cancer or infection with the human immunodeficiency virus (HIV) (Wang, McLeod, and Weinshilboum 2011). Widespread implementation of clinically useful pharmacogenetic tests can save healthcare dollars by guiding clinicians toward drug regimens that have a lower likelihood of failure or toxicity (Ventola 2011; Winner et al. 2013). These tests can also assist clinicians with making treatment decisions, such as when to use cytotoxic chemotherapy versus hormonal therapy for the treatment of certain forms of breast cancer (Carlson and Roth 2013).

As pharmacogenetic tests become more widely available and less expensive due to technological advances, it is reasonable to suspect that the utilization of these tests will increase (Frueh 2010). As this occurs, it will become more critical for health information professionals to recognize and understand the pharmacogenomic tests that are available and how to document its usage properly. Until relatively recently, it has been difficult to document specific pharmacogenomic tests using current procedural technology (CPT) codes. The purpose of this concise review is two-fold. Past and present difficulties with documenting these tests will be presented and discussed. Select examples of currently available pharmacogenomic tests and their corresponding CPT codes will also be addressed. The ultimate goal is to highlight pharmacogenomic testing and its relevance to health information professionals. This review aims to provide health information professionals with a better understanding and perspective of pharmacogenomic testing that will allow for better, more accurate documentation for the purposes of billing and record keeping.

For this review, published reports on pharmacogenomic testing from the PubMed and OVID Medline databases were utilized. Documents and official CPT updates released from the American Medical Association (AMA) were used to prepare Table I.

PAST AND PRESENT

Pharmacogenomic testing has only been available since the early to mid-2000s, with the first FDA approved test coming in 2005 (Ventola 2011). Early adopters had difficulty documenting such procedures using CPT codes for two key reasons: unfamiliarity with the new tests and non-specific coding practices. It is not known precisely how often these tests were utilized after they debuted, but it is reasonable to suspect that they were not widely

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employed by practitioners. Surveys published in 2009 showed slow adoption of pharmacogenomic tests in Europe, Australia, and New Zealand (Sheffield and Phillimore 2009). There were scant clinical outcomes data to justify their cost, and much of the healthcare community was likely unaware of these tests when they first debuted (McKinnon, Ward, and Sorich 2007). It should be noted that to the best of our knowledge, comprehensive rates of pharmacogenomic testing in the United States have not been reported. Early on, there were few resources available for those in health information management to consult when documenting these tests. It was also difficult to accurately and appropriately document these tests due to a lack of specific CPT codes (Pharmacogenomic Testing in Current Clinical Practice: Implementation in the Clinical Laboratory 2011). At first, the AMA did not assign these tests specific CPT codes in their published resources as they were considered “molecular pathology procedures”. Prior to 2012, pharmacogenomic tests were often documented as such, which had many consequences. First, individual pharmacogenomic tests could not be documented efficiently or accurately, and were often loosely differentiated by “stacking” various codes for specific tests. This lack of specificity made it very difficult to have a universally accepted method for coding specific pharmacogenetic tests. Non-specific coding also made tracking the utilization trends and the cost-efficacy of these tests outside of clinical trials more difficult. Next, correct and accurate reimbursement for using these tests would be in jeopardy because of the non-specific manner in which the tests were documented. When the first pharmacogenetic tests became available, they were rarely covered by any insurance plans, and the cost was often paid by the patients themselves. However, as more clinical studies showed the benefits that pharmacogenomic testing can offer to patients in specific circumstances, many insurance entities began to cover select tests (Hresko and Haga 2012). This necessitated improved documentation practices for billing, reimbursement, and recordkeeping purposes. The lack of specific procedural codes led to confusion and consternation between clinicians and health information professionals alike.

The issues began to be addressed in 2012, when the AMA acted on requests to assign many of these pharmacogenomic tests unique CPT codes for documentation purposes (Ohara 2012). These CPT codes are for pharmacogenomic tests that detect specific gene variants known to impact drug therapy. The new codes went into effect in 2013. Table I shows select pharmacogenomic tests that have unique CPT codes available for documentation purposes, as well as a brief description of the test. It is important to note that additional pharmacogenomic tests are available; however, many have not been assigned a specific CPT code. Some pharmacogenomic tests are actually comprised of multiple individual tests that are performed and analyzed with a proprietary algorithm to assist in therapeutic decision making. An example of this includes multi-gene combinatorial pharmacogenomic testing for the purposes of guiding treatment of depression or breast cancer. A few healthcare management entities have even opted to cover expensive genomic testing packages which utilize multiple pharmacogenomic tests to guide therapy for specific patient populations (U.S. Department of Veterans Affairs Awards GeneSight® Federal Supply Schedule Contract 2014). These pharmacogenetic test packages often need to be documented with multiple CPT codes as each code documents a separate test that is performed as part of the

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complete package. The results of the individual tests are generally used in proprietary algorithms to generate treatment recommendations for practitioners (Hall-Flavin et al. 2012).

CONCLUSIONS

Pharmacogenetic testing continues to pose challenges for health information professionals. Documenting the use of pharmacogenetic tests accurately can still be difficult since new tests may not have unique CPT codes available yet. Genomic services and pharmacogenetic test packages can further complicate the documentation process because a single CPT code is not available, instead multiple codes need to be used. This challenge is likely to persist as it is probable that future drugs may require new genomic tests to be developed and introduced for ensured safety. To overcome the documentation challenges posed by pharmacogenomic testing, it is important to know that many pharmacogenomic tests do have specific codes available. It is also important to stay up to date with annual CPT code changes involving pharmacogenomics testing in general. The AMA does address concerns with documenting pharmacogenomic testing via CPT codes sporadically, with the revisions in 2012 being one of the largest overhauls seen yet. It may be a good option to contact those companies that offer pharmacogenomic test packages that are based on multiple “sub-tests” to inquire what specific CPT codes are appropriate for documentation. These companies are often intimately familiar with the exact codes necessary to document for proper recordkeeping and reimbursement purposes.

Currently, there is very little published research concerning the impact of more specific coding has had on the efficiency of documentation. In general, the topic of pharmacogenomic test documentation is relatively unexplored. The lack of research in this area leads to difficulty when attempting to validate the impact of any procedural code changes with respect to pharmacogenomics testing. As personalized medicine receives more attention from the healthcare community, it is likely that pharmacogenetic testing will become more prevalent. Being a relatively new approach to delivering optimal and individualized patient care, pharmacogenomics is still not well understood by many in healthcare (Mrazek and Lerman 2011). Its potential to improve the lives and healthcare outcomes of patients makes the understanding of pharmacogenetic tests critical. Proper documentation of pharmacogenetic testing is of great importance to health information professionals and will continue to be for the foreseeable future.

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Table I

Examples of pharmacogenomic tests with associated CPT codes for identification and documentation.

CPT Code	Test	Description of Test
81225	CYP2C19 genotyping	Detects genetic variants of *CYP2C19* associated with variable drug metabolism
81226	CYP2D6 genotyping	Detects genetic variants of *CYP2D6* associated with variable drug metabolism
81227	CYP2C9 genotyping	Detects genetic variants of *CYP2C9* associated with variable drug metabolism
81355	VKORC1 testing	Detects genetic variants of *VKORC1* associated with warfarin therapy
81350	UGT1A1 genotyping	Detects genetic variants of *UGT1A1* associated with irinotecan toxicity
84431	11-dehydro thromboxane B2	Measures 11-dehydro thromboxane B2 in urine to determine aspirin resistance
81381	HLA B*57:01	Detects the *HLA B*57:01* allele associated with abacavir toxicity
82955	G6PD quantitative	Measures glucose-6-phosphate dehydrogenase activity
81210	BRAF mutation testing	Detects mutations in *BRAF* associated with BRAF inhibitor therapy
81275	KRAS mutation testing	Detects mutations in *KRAS* associated with KRAS inhibitor therapy
88360	HER2 expression	Detects the expression of HER2 to guide therapy with HER2 inhibitors
81235	EGFR mutation testing	Detects mutations in *EGFR* associated with EGFR inhibitor therapy
81220	CFTR profile	Detects mutations in *CFTR*, which is necessary prior to therapy with ivacaftor
87999	HIV-1 tropism testing	Determines HIV tropism for chemokine receptor 5 [CCR5], and/or chemokine receptor 4 [CXCR4] to guide therapy with receptor antagonists
81287	MGMT gene methylation	Determines *MGMT* methylation status to guide therapy with alkylating agents

Note: some tests may be components of multi-test panels offered by various companies.

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