WORKING
PAPER

Volume Growth in Medicare

An Investigation of Ten Physicians' Services

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WR-6310-ASPE

December 2008

Prepared for the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services

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Contract: HHS-100-03-0019

RAND Health

The Urban Institute

Preface

In this project a team of RAND and Urban Institute Researchers sought to identify ten medical services with significant increases in utilization, and in associated spending, among Medicare beneficiaries from 2000 to 2006. The researchers examined reasons for the observed growth, exploring whether or not the underlying spending increases were related to new clinical evidence of benefit, reimbursement, epidemiological factors, patient demand, provider uptake, or coverage decisions.

This work was sponsored by the Assistant Secretary for Planning and Evaluation under Task Order HHSP23320070004T, Contract number 100-03-0019, for which Dr. Laurie Feinberg served as project officer.

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Executive Summary

Medicare's Sustainable Growth Rate (SGR) is a target rate of growth in spending for physicians' services. Payments for physicians' services are supposed to automatically adjust in response to actual spending falling either above or below the target. But since 2002, when the SGR policy led to a 4.8 percent reduction in payment rates, policymakers have been searching for ways to avoid fee reductions without adding to the Medicare program's overall expenditures. Recently, the Medicare Payment Advisory Commission (MedPAC) examined alternative mechanisms for controlling expenditures on physicians, but did not propose any single alternative. As a result, Congress overrode the SGR policy for the sixth time this year to give physicians small fee increases and found various policy changes to offset those costs. Each year, however, the costs of circumventing the SGR policy increase as do demands for a permanent "fix" to the SGR.

In this paper, we examined the underlying causes of growth in ten medical services that saw significant increases in utilization and associated spending among Medicare beneficiaries between 2000 and 2006. We considered the role that multiple factors such as the aging of the population, the development of new clinical standards of practice, and financial incentives could have on explaining the observed growth. Scans of guidelines and literature summaries were augmented by structured interviews with national experts in relevant disciplines. The methods we developed to investigate the observed growth for these ten medical services could inform alternatives to Medicare's SGR Policy.

Methods

To shed light on the underlying causes of volume growth, we sought to identify ten services with significant increases in utilization, and associated spending, among Medicare beneficiaries between 2000 and 2006. We used a combination of qualitative and quantitative methods to select the ten services for analysis. Our quantitative objective was to identify services for which Medicare expenditures were increasing rapidly and for which significant sums were spent by Medicare. We used data from the Physician/Supplier Procedure Summary files for 2000 and 2006 to examine these two

aspects of Medicare physician spending. We also sought to represent a variety of clinical areas covering a range of diseases and conditions – particularly diseases and conditions associated with substantial morbidity or mortality – in our final list of ten services.

We then explored the reasons for growth in these ten services. Our examination of the factors leading to the increased use of physicians' services had three interrelated phases: we first selected and interviewed relevant clinical experts, then we reviewed sources of information on changes in the clinical indication for the services, and finally we conducted supplemental searches to flesh out other reasons for growth suggested by our clinical experts.

Results

Our syntheses revealed that clinical factors, service diffusion, and financial factors drove growth to varying degrees across the ten services. (Table 3 in our full report summarizes these reasons for the growth in each of our ten services and classifies it as a major reason for growth, a contributing reason for growth, or not a reason for growth.) Interestingly, clinical factors and patient demand were factors for eight of the services we studied, but were major factors for only three. New technologies and new scientific evidence stimulated the growth of two services and patient demand drove six. A change in the size of the potentially eligible population was not a major factor for any of the services. Nevertheless, for most services, the potentially eligible population was quite large, setting the stage for rapid growth once other factors came into play. In contrast, financial factors or increased uptake by providers were factors for all ten services and were major factors for seven. Among major financial factors, Medicare coverage decisions influenced two services and reimbursement rates influenced two others. Overall, uptake by providers was the single most important factor, being a major driver of growth for seven services. Provider uptake and financial factors appeared synergistic, such that providers shifted toward providing more profitable services rather than alternatives and established in some cases independent specialty centers, in part to increase revenue.

Conclusions and Policy Implications

Our results point to the important role that the diffusion of new technology and financial factors play in increasing expenditures for physicians' services – even in the absence of any new clinical evidence or epidemiologic trends. One reason this is the case is that consensus about the appropriate use of most services and procedures simply does not exist, leaving room for other factors to influence care patterns. But determining appropriateness requires rigorous reviews of the clinical evidence, expert panels, or other measures that are usually time- and resource-intensive. In addition, there are potentially a huge number of services that would benefit from examination: it is not simply new technologies that must be reviewed but new and expanded uses of existing technology and services. While over the longer term Congress might appropriate funding for the Centers for Medicare and Medicaid Services (CMS) or another government agency to conduct reviews of appropriateness and cost-effectiveness, other methods will be needed to rationalize spending growth in physicians' services over the near term.

Fortunately, our results do point to a number of ways to address potentially inappropriate growth in service use – and ways not to address it. We'll start with what does not appear to be working. Cutting or increasing the payment for all services uniformly, as the SGR policy does, is not producing greater efficiency. Among the ten high-growth services we examined some were clearly delivering high value while others were not. Indeed, we heard repeatedly that declining (relative) payments for Evaluation and Management (E&M) services caused by the SGR were partially to blame for physicians' attempt to make up in procedure volume what they were not compensated for during regular office visits. Second, we cannot rely on existing clinical guidelines to determine what types of volume growth are appropriate; guidelines are simply not specific enough to translate directly into appropriateness measures, a conclusion that others have also drawn when examining CMS coverage decisions.

Annual review of growing codes. We would, however, recommend implementation of a multi-pronged approach to controlling spending growth, rooted in the methods we piloted in this project. Specifically, the methods developed in this study for identifying high-growth services could be very valuable for targeting reviews and policy changes. While there are over 6000 codes on the Current Procedural Terminology (CPT)

schedule, the top 600 account for more than 90 percent of spending and those 600 can be grouped into a much smaller number of code "families." It is reasonable to believe that the top 600 codes could be systematically reviewed on an annual basis.

The annual review of growth in the top codes could incorporate clinical expert advice. We found during this study that that the clinical experts we interviewed were fully capable of absorbing the data presented to them during interviews about growth in service use and reflecting on multiple causes of that growth. Our interviews revealed multiple types of actionable information, such as:

- services for which the relative value units (RVUs) which determine payment, and especially the practice expense RVUs, might be out of line with true underlying resource costs, making the services relatively profitable;
- intense manufacturer marketing and promotion efforts that signaled over-valued services that were growing for reasons unrelated to concrete evidence of benefit; and
- new technologies being billed and delivered under existing codes that may not provide sufficient benefit.

In addition, the growth in imaging reinforced the importance of acting on the recommendations of other researchers and government bodies who have sounded warnings about these services. All of these findings could be followed-up on and adjustments made to payment rates, billing codes, coverage criteria, or other Medicare policies. With respect to practice expenses, we would also note that the evidence suggests that they should be reduced in a cost-saving way, rather than the budget-neutral way that RVU changes are currently implemented.

Systemic changes to address growth. Moreover, there are a few ways in which CMS could begin to address more systematic problems with physicians' services growth. First, we were repeatedly told that the payment differentials between E&M services on the one hand and tests and procedures on the other were contributing to inefficient practice patterns. Although the principle behind the Resource-Based Relative Value Scale (RBRVS) system of reimbursing at the level of the average costs of each service is admirable, failure to estimate average prices correctly is clearly having perverse effects. E&M rates are not keeping up with new technologies that are being added to the fee

schedule. They should be increased so that providers' incentives to over-utilize tests and procedures to increase revenue are mitigated and so that managing chronic diseases becomes more remunerative. Of course, this also means that fees for over-valued tests and procedures must be reduced – otherwise there is a risk that volume growth in both areas will continue. Second, CMS should seek the authority to augment the local medical review procedures conducted by the Medicare Administrative Contractors. These procedures could include the types of prior authorization activities that private insurers are implementing to limit technology use to indications for which it has been proven to be effective. Consistent with other efforts that CMS is considering, such as case management payments for "medical homes," payments for episodes of care, and incentive payments for achieving cost and quality targets, these measures would move the Medicare program in the direction of rewarding value, rather than simply reimbursing costs. Over the long term, this is the only way for the program to break out of the cycle of constantly adjusting thousands of individual service prices in an attempt to align providers' incentives with those of the country as a whole.

Acknowledgments

We would like to thank Paul Shekelle and Laurie Feinberg for comments on an earlier draft and José Escarce for his input in selecting the ten conditions. We would also like to thank the physicians who consented to be interviewed for this project including: Barbara A. Phillips, MD, MSPH; David C. Miller, M.D., M.P.H.; Sandra L. Wong, M.D., M.S.; Ron L. Moy, MD; Brian Olshansky, MD; Michael W. Rich, MD; Joseph S. Alpert, MD; John T. Wei, MD, MSc.; Patrick J. Strollo, Jr., M.S., M.D.; David D. Kilmer, MD; Paul P. Lee, MD, JD; Richard W. Rosenquist, M.D.; J. D. Bartleson, MD; Eugene J. Carragee, M.D; Timothy R. Lubenow, M.D.; George A. Williams, MD; Franz J. Wippold, II, M.D.; Allan H. Goroll, M.D., FACP; Rebecca D. Elon, M.D., M.P.H.; and a urologist who declined to be listed by name. Any remaining errors are our own, and we would welcome feedback on this document.

Introduction

Medicare's Sustainable Growth Rate (SGR) is a target rate of growth in spending for physicians' services. Payments for physicians' services are supposed to automatically adjust in response to actual spending falling either above or below the target. But since 2002, when the SGR policy led to a 4.8 percent reduction in payment rates, policymakers have been searching for ways to avoid fee reductions without adding to the Medicare program's overall expenditures. Recently, the Medicare Payment Advisory Commission (MedPAC) examined alternative mechanisms for controlling expenditures on physicians, but did not propose any single alternative (MedPAC, 2007). As a result, Congress overrode the SGR policy for the sixth time this year to give physicians small fee increases and found various policy changes to offset those costs. Each year, however, the costs of circumventing the SGR policy increase as do demands for a permanent "fix" to the SGR.

In this paper, we examined the underlying causes of growth in ten medical services that saw significant increases in utilization and associated spending among Medicare beneficiaries between 2000 and 2006. We considered the role that multiple factors such as the aging of the population, the development of new clinical standards of practice, and financial incentives could have on explaining the observed growth. Scans of guidelines and literature summaries were augmented by structured interviews with national experts in relevant disciplines. The methods we developed to investigate the observed growth for these ten medical services could inform alternatives to Medicare's SGR Policy.

Background

The SGR itself was an attempt to improve upon prior payment update systems that were also considered broken. The path to the SGR began in the late 1980s when Medicare developed the resource-based relative value scale (RBRVS) system to replace the historical "usual and customary" fees that were considered inequitable and did not reflect the underlying costs of delivering services. The new fee schedule specified the relative value units (RVUs) associated with each physician service; those RVUs reflect

the resources needed to provide that service. The RVUs are then multiplied by a dollar conversion factor to determine payment. The conversion factor changes annually in line with formulas set out in legislation: the SGR policy replaced the VPS (Volume Performance Standard) policy formula that also theoretically governed fee schedule updates by tying them to a target rate of growth.

The implications of the fee schedule update policy though are very real: in 2007, Medicare spending totaled $426 billion, with spending on physicians' services accounting for roughly 28% of the total. And while the SGR attempts to limit price increases, the volume of services has been rising rapidly. Indeed, within the first ten years after the implementation of the RBRVS, the overall RVU volume per beneficiary for physicians' work grew by 50% (Maxwell, 2007). The Congressional Budget Office found that growth in Medicare's per-beneficiary spending was largely explained by growth in the volume and intensity of physicians' services, rather than by changes in Medicare's payment rates (CBO, 2007). Moreover, the observed growth in volume is not equal across medical services. The RVU volume per beneficiary has grown far more drastically for medical imaging and certain procedures than it has for evaluation and management services (Maxwell, 2007). Yet, the SGR formula decreases the conversion factor to all services and all physicians equally, not just the ones driving the increased spending.

Congress' practice of circumventing the SGR policy year after year without repealing the system outright also makes the problem harder to fix: by 2010 the formula may dictate payment cuts upwards of 21% and, to avoid those cuts, funds will need to be found elsewhere in the budget unless new sources of funding are found (Kaiser Family Foundation, 2008). But there is great disagreement about replacements to the SGR, how to determine when volume growth is desirable, the utility of expenditure targets in general, and whether or not a single conversion factor should be uniformly applied to all services (MedPAC, 2007). For example, in 2007, the House passed the Children's Health and Medicare Protection Act (CHAMP, H.R. 3162) which included a proposal to establish separate conversion factors for difference service categories, but the Senate did not. The debate will no doubt resume again in 2009.

Methods

To shed light on the underlying causes of volume growth, we sought to identify ten services with significant increases in utilization, and associated spending, among Medicare beneficiaries between 2000 and 2006. Details about how the services were chosen and how reasons for growth were probed are provided below.

Choice of services

We used a combination of qualitative and quantitative methods to select the ten services for analysis. Our quantitative objective was to identify services for which Medicare expenditures were increasing rapidly and for which significant sums were spent by Medicare. We used data from the Physician/Supplier Procedure Summary (PSPS) files for 2000 and 2006 to examine these two aspects of Medicare physician spending. We also sought to represent a variety of clinical areas covering a range of diseases and conditions – particularly diseases and conditions associated with substantial morbidity or mortality – in our final list of ten services.

In order to keep the number of potential candidates for the study manageable, we focused on the 600 Current Procedural Terminology (CPT) codes that had the highest allowed charges per beneficiary in 2006. These 600 codes accounted for 91 percent of Medicare allowed charges for physician services in 2006. The overall growth in allowed charges per beneficiary for these 600 codes between 2000 and 2006 was 51 percent, netting out the increases in the Medicare payment conversion factor. Two types of services paid according to the resource-based relative value scale were not considered for inclusion. First, although E&M services represent a large share of Medicare physician spending, the lack of information related to the specific reasons for the services precluded them from being suitable for this study. Second, we did not consider services for which the growth was commonly known to be desirable and encouraged, such as influenza vaccination or bone density scans.

Among the remaining codes, we considered those for which allowed charges per beneficiary were close to the top of the list of 600 CPT codes and those that had grown by at least 100% from 2000 to 2006. We selected a set of 16 codes as candidates.

Following CPT definitions, we treated CTs and MRIs for different regions of the body (e.g., brain and lumbar/spine) as distinct services. The final review of codes was then performed in order to choose a diverse set of codes and narrow the list down to a tractable set of ten. Each of these ten services is often closely related to other CPT codes and looking at the ten without looking at these related codes could be misleading. Therefore, we identified these related CPT codes to create "families" of codes through a careful review of the CPT manual, using additional information from leading insurance companies and websites of academic medical centers.

The ten families of codes that resulted from this process are shown in Table 1, along with allowed charges per beneficiary in 2000 and 2006, the percent change in allowed charges per beneficiary, and the CPT codes that make up each family of codes. A brief description of each family of services is provided in Table 2. These ten services families accounted for 7 percent of 2006 allowed charges within the initial 600 CPT codes and allowed charges per beneficiary for these ten services grew by 142 percent between 2000 and 2006. Within the services used in the study, the largest increases occurred among procedures for benign prostatic hyperplasia (1991 percent) and spinal injection procedures for back pain (731 percent).

Examining Factors Underlying Increased Utilization of Services

Our examination of the factors leading to the increased use of physicians' services had three interrelated phases: we first selected and interviewed relevant clinical experts, then we reviewed sources of information on changes in the clinical indication for the services, and finally we conducted supplemental searches to flesh out other reasons for growth suggested by our clinical experts.

Selecting and Interviewing Clinical Experts: The objective of this step was to generate hypotheses about how and why the utilization of each of the ten services increased. These hypotheses were later explored through our scan of guidelines and summary literature, discussed below. For each of the ten services, we interviewed a minimum of four physicians: at least two specialists or subspecialists in relevant fields, one geriatrician, and one general internist.

Table 1

Growth in Medicare Allowed Charges per Beneficiary for 10 Selected High Growth Service Categories

	Allowed Charges per Beneficiary			
Service Category	**2000**	**2006***	**% Change**	**CPT Codes**
Cardiac Defibrillator Implantation to Prevent Sudden Death	0.70	1.87	165%	33249, 33245
Cardiac Stress Testing for Coronary Artery Disease	20.87	46.53	123%	78465, 78478, 78480
CT/MRI Scans: Brain	17.36	27.05	56%	70470, 70460, 70552, 70551, 70450, 70553
CT/MRI Scans: Lumbar/Spine	8.63	16.91	96%	72132, 72131, 72148, 72149, 72158, 72133
Diagnosis and Medication Therapy for Macular Degeneration	4.48	14.57	225%	67028, 92135, 92235
Electrodiagnostic Testing for Nerve Problems	3.43	12.21	256%	95900, 95904, 95903
Mohs Surgery for Skin Cancer	3.96	10.04	154%	17307, 17306, 17305, 17304
Polysomnography for Sleep Apnea	1.36	7.12	422%	95810, 95811
Procedures for Benign Prostatic Hyperplasia	0.30	6.32	1991%	52648, 52647, 53852, 53850
Spinal Injection Procedures for Back Pain	0.89	7.43	731%	62311, 64475, 64483, 76005
Total for Selected Services	62.00	150.05	142%	
Total for All Services	1577.00	2205.99	40%	

NOTE: Mohs' codes 17311-17315 replaced codes 17304-17310, starting in 2007;
2000 pop =30.478 million 2006 pop = 32,908 million;
All CPT codes in 2000 and 2006 PSPS files
*Net of conversion factor increase

Table 2

Brief Description of Ten Selected Services

Service Category	Description
Cardiac Defibrillator Implantation to Prevent Sudden Death	An implantable cardioverter defibrillator (ICD) continuously senses and analyzes the cardiac rhythm. When the unit detects a potentially lethal rhythm, it delivers electrical shocks to the heart, hopefully restoring normal rhythm.
Cardiac Stress Testing for Coronary Artery Disease	Cardiac stress testing detects reduced blood flow to cardiac muscle. They are used to diagnose heart attacks and coronary artery disease, assess prognosis, and determine the appropriate course of treatment.
CT/MRI Scans: Brain	Computed tomography (CT) and magnetic resonance imaging (MRI) are used to image the brain. They are helpful in a variety of clinical situations, including confusion, weakness, head injury, atypical headache, stroke, bleeding into the brain, brain tumor, swelling of the brain, etc.
CT/MRI Scans: Lumbar/Spine	CT and MRI are also used to image the spine, particularly the lower back (lumbar spine) where pain is most common. They can detect tumors, narrowing of the spinal canal, arthritis and other degenerative changes of the spine, disk problems, pinched spinal nerves, etc.
Diagnosis and Medication Therapy for Macular Degeneration	We analyzed both the imaging and treatments associated with caring for age-related macular degeneration. A new treatment for neovascular age-related macular degeneration became available recently, monoclonal antibodies against Vascular Endothelial Growth Factor.
Electrodiagnostic Testing for Nerve Problems	Electrodiagnostic tests include nerve conduction studies and electromyography. They are used to determine the presence, location, and nature of disorders of the nerves and muscles.
Mohs Surgery for Skin Cancer	Mohs microscopic surgery is used to remove basal cell and squamous cell carcinomas of the skin. In Mohs surgery, the tumor is resected in one to five or more stages until the surgical margin is confirmed to be completely clear of tumor.
Polysomnography for Sleep Apnea	Polysomnography monitors a variety of physiological parameters during sleep. Among Medicare beneficiaries, the overwhelming majority are for the diagnosis or management of obstructive sleep apnea.
Procedures for Benign Prostatic Hyperplasia	Benign prostatic hyperplasia (BPH) is an enlargement of the prostate that blocks urine flow. Several relatively new, less-invasive procedures use a variety of energy sources, such as electricity, radiofrequency waves, microwaves, and lasers to coagulate, vaporize, or resect prostate tissue.
Spinal Injection Procedures for Back Pain	Injections can be used to both diagnose the source of back pain and provide pain relief. Common types of injections include: epidural steroids, facet joint blocks, facet rhizotomies, sacroiliac joint blocks, and selective nerve root blocks.

We sought physicians with the following characteristics: (1) they treat patients who are candidates for the service on a regular basis; (2) they are from a variety of practice environments around the country; (3) they are recognized as national experts within their specialty. Wherever possible, we selected individuals who were recommended by their specialty society, who had participated in developing relevant clinical guidelines or quality measures, or who held leadership positions in their fields (such as editors of major journals or textbooks, or residency program directors). Several had published articles on health services research topics, suggesting a familiarity with utilization patterns as a research question. In all, we interviewed 20 physicians: two pulmonologists with expertise in sleep medicine, three urologists, one Mohs surgeon, one surgical oncologist with expertise in malignancies of the skin, two general cardiologists, one electrophysiologist, one physiatrist with expertise in electrodiagnosis, one neurologist with expertise in pain management, one orthopedist with expertise in spinal issues, one radiologist with expertise in the central nervous system, two anesthesiologists with expertise in pain management, one general ophthalmologist, one retina specialist, one geriatrician in a community practice setting, and one general internist who is the editor of a major primary care textbook. The experts are named in the acknowledgments and their affiliations are provided in an appendix.

The physicians were interviewed about services relevant to their respective specialties, from one to ten services each. We sent a list of open-ended questions to review in advance then discussed responses during the interview. The questions were the same for each topic. First, we asked general questions about how much they believed utilization of the service had grown and why. Next, we asked specific questions about what role each of the following types of factors may have played: whether the clinical indications for the service had changed, whether demographic trends had affected the number of eligible patients, whether new evidence supporting use had emerged, whether providers had gained increasing knowledge or expertise in the service, whether the availability of resources involved in using the services appeared to have affected use, whether payment systems appeared to have influenced the use of this service over clinical alternatives, and whether any other factors might have contributed. Each interviewee was also asked to identify key literature or other sources to corroborate their statements, such

as research studies, guidelines, appropriateness measures, National Coverage Decisions, etc. The interviews generally lasted from one half to three hours, depending on the number of topics covered.

Systematically Searching for Information on Changes in the Indications for Each Services: The objective of this step was to identify clinical treatment guidelines and other high-quality literature that reviewed the evidence for each service, the appropriate indications for its use, and whether these indications had changed during or shortly before the 2000 to 2006 period. This step generally occurred before or in tandem with the interviews discussed above. For each of the ten services and associated clinical disorders, physicians on the research team developed search terms, applied the terms to data sources listed below, and then determined relevance of search results by examining titles then abstracts, summaries, and document text. Documents published before 1998 were excluded. Data sources included: The Agency for Health Care Research and Quality (AHRQ) National Guidelines Clearinghouse; The AHRQ Evidence-based Practice Centers' (EPC) reports; AHRQ's National Quality Measures Clearinghouse; the U.K. Cochrane Library Centre for Reviews and Dissemination, DARE; United Kingdom National Institute for Health and Clinical Excellence, clinical guidance documents and guidelines; Canadian Agency for Drugs and Technologies in Health, technology reviews; National Committee for Quality Assurance, Healthcare Effectiveness Data and Information Set Measures, National Quality Forum website; MEDLINE searches restricted to limited to specific journals (Evidence-Based Medicine, ACP Journal Club, Cochrane Database of Systematic Reviews, the New England Journal of Medicine), AND publication type "review" AND published in the last ten years; and, when relevant, the Food and Drug Administration website for information on the approval of specific medications. When these various sources failed to provide much information on a service, we conducted a supplemental MEDLINE search (publication types clinical trial, meta-analysis, randomized controlled trial, practice guideline, review, and published in the last ten years).

Supplemental Searches for Background Information and Contributors to Utilization Trends: We supplemented the formal searches discussed above with less structured search methods for three basic reasons. First, sometimes the formal searches did not yield sufficient information. Often widespread dissemination had occurred before, or even in the absence of, high-quality research studies or published guidelines. For example, there are no recent guidelines for Mohs surgery in the National Guidelines Clearinghouse. Yet Mohs is widely accepted as an appropriate treatment for basal cell carcinoma, based on surgical case series published more than two decades ago. Second, we needed to identify background information on the services, such as associated clinical conditions, how the service works, when it was developed and historical uses, how the service is billed, alternatives to the service, and emerging trends. Guidelines and evidence reviews generally omit such information. Third, interviewees often identified contributors to utilization trends that were not reflected in the guidelines or evidence reviews, and we sought to corroborate their hypotheses with publicly available sources or peer-reviewed papers whenever possible.

These less structured searches involved the following methods. We used the supplemental MEDLINE search technique described above to identify recent non-systematic reviews, which often provided background information as well as references to major epidemiological studies and randomized controlled trials. We used Up-To-Date and the PIER Decision Support resource from the American College of Physicians in a similar manner as the non-systematic reviews. When examining results from the supplemental searches, we used the PubMed "Related Articles" feature to identify additional papers. In some instances, epidemiologic data and resources corroborating experts' points were found on the internet, such as major causes of death in the Medicare age group, Medicare National Coverage Decisions, and Relative Value Units for each service.

Summarizing Factors Contributing to the Growth of Each Service: Physicians on the research team reviewed transcripts from the expert interviews, literature the experts had recommended, the results of the systematic searches for evidence, and the results of the supplemental searches, then wrote brief syntheses for each service. The summaries covered the conditions associated with the use of the service, description of service and

major indications, growth in volume for the CPT codes associated with the service, and factors that, in their judgment, appeared to be major contributors to growth. Whenever possible, they relied on public or peer-reviewed sources to support factors contributing to growth, unless there were no such sources and there was a general consensus among interviewees that a factor was a major contributor to growth. These syntheses can be found in the Appendices to this report.

Results

Our syntheses revealed that clinical factors, service diffusion, and financial factors drove growth to varying degrees across the ten services. Table 3 summarizes these reasons for the growth of each of our ten services and classifies it as a major reason for growth, a contributing reason for growth, or not a reason for growth. Each of these conclusions about reasons for growth is explained in further detail below and a few examples are provided from our set of ten services.

Table 3
Reasons for Growth in Selected Services

	Service Category									
	Cardiac Defibrillator Implantation to Prevent Sudden Death	Cardiac Stress Testing for Coronary Artery Disease	CT/MRI of the Brain	CT/MRI of the Lumbar Spine	Diagnosis and Medication Therapy for Macular Degeneration	Electro-diagnostic Testing for Nerve Problems	Mohs Surgery for Skin Cancer	Polysomno-graphy for Sleep Apnea	Procedures for Benign Prostatic Hyperplasia	Spinal Injection Procedures for Back Pain
1. Clinical Factors:										
a.Epidemiologic trends: increasing age, obesity, or other trends affecting the numbers who might benefit from the service							Contri-buting	Contri-buting		
b.New evidence: potential benefits to patients are greater than previously appreciated or service benefits patients who were not considered candidates for it before	Major				Major					
2. Diffusion:										
a.Patient demand: patients have greater awareness or interest			Contri-buting	Contri-buting			Contri-buting	Contri-buting	Major	Contri-buting
b.Provider uptake: providers have greater awareness, interest, or experience/skill		Major	Major	Major		Major	Contri-buting	Major	Major	Major
3. Financial Factors:										
a.Payment structure/RVUs: more lucrative than other services		Contri-buting			Contri-buting	Major	Contri-buting	Contri-buting	Major	Contri-buting
b.Medicare coverage decisions: new rules affect service use	Major					Contri-buting		Major		

A. Clinical Factors

As shown in Table 3, across the ten services, clinical factors were major drivers of growth for two (angiogenesis inhibitors for AMD, and ICDs) and contributors for two (polysomnography and Mohs surgery).

Epidemiologic Factors: Changes in the epidemiology of the associated clinical disorders, i.e., incidence between 2000 and 2006, appeared to contribute modestly to growth of polysomnography and Mohs surgery. Obesity rates have nearly doubled nationally over the last ten years (CDC Obesity Trends), likely leading to a substantial increase in the prevalence of obstructive sleep apnea (OSA). Skin cancer also increased relatively rapidly between 2000 and 2006 (Alam, 2001; Ceilley, 2006; SEER, 2008). However, these trends were far more modest than the rate of growth in these services.

For many of the services, there were large reservoirs of potentially eligible patients, i.e., a high prevalence of the associated clinical disorders, which *permitted* rapid growth to occur when other factors came into play. For polysomnography, symptomatic but undiagnosed sleep apnea appears to affect 5% percent of U.S. adults, and the prevalence may be 2 to 4 times higher in the Medicare age group (Young, 2002). Five hundred thousand Medicare beneficiaries are now thought eligible for ICDs due to the prevalence of cardiomyopathy and its attendant risks of sudden cardiac death, for which there are no other effective preventative treatments (McClellan, 2005). Benign prostatic hyperplasia is a nearly universal consequence of aging. About 1.75 million individuals, most of them in the Medicare age group, are affected by the neovascular form of the age-related macular degeneration, which responds to angiogenesis inhibitors and for which previous therapies were suboptimal (Klein, 1992). For the remaining services, the number of potentially eligible patients is large but it is less clear that they were underdiagnosed or undertreated.

New Technology or New Scientific Evidence of Benefit to Patients: Angiogenesis inhibitors for macular degeneration represent entirely new clinical advances that occurred shortly before or during the 2000 to 2006 period. While rigorous clinical trials do support the use of the angiogenesis inhibitors, growth in utilization started before those trials were actually published. A small network of retina specialists – about 2000 nationally – facilitated rapid dissemination of

evidence from the clinical trials that supported the immediate application of the new anti-angiogenic factor drugs for a serious problem for which there had not been an effective treatment available.

New scientific evidence was a major factor for only one service other than the angiogenesis inhibitors. ICDs were an established technology before 2000, but major new research extended their use to entirely new groups of patients (those with cardiomyopathy) between 2000 and 2006, and this research appeared to directly stimulate the observed growth. New technologies and changes to the scientific evidence were later reflected in relevant clinical guidelines, but there is no evidence that guidelines drove the growth per se.

B. Diffusion

Of the ten services, eight services grew due to increased patient demand or provider uptake of the service.

Patient Demand: We found that greater patient awareness of, or interest in, the service contributed to growth in six out of our ten services. For example, it was a major driver of growth in procedures for BPH because patients often have strong preferences for the newer procedures over medications and TURP. Some patients may wish to avoid the costs, side effects, and hassles associated with medication therapy, or have found the medications ineffective. At the same time, they may prefer not to undergo an operation that entails significant risks and a several-day hospitalization. Thus, a reservoir of undertreated patients with bothersome BPH symptoms explains some of the rapid uptake of the less invasive procedures. Demand for advanced imaging – essentially to "rule-out" serious conditions to provide enhanced patient assurance – has also increased according to our experts, spurred in some cases by direct-to-consumer advertising.

Provider Uptake: We found that actions taken by providers were major drivers of increased volume for seven of the services we examined and a contributing factor in the growth of one other. These actions took many forms, but all of them are fundamentally related to the profitability of the service. The first is simply whether the number of providers willing and able to perform the service increased over the study period. This appeared to be a major factor that

explains some of the differential growth in nuclear rather than echocardiographic stress testing: nuclear training is much easier to acquire, with most cardiologists being proficient to provide the service independently by the end of fellowship. Growth in the number of trained providers appeared to be a contributor for Mohs surgery, given a substantial increase in the number of fellows in Mohs training programs coupled with growing use of the method by surgeons who are not formally trained.

Second, experts thought that in the period 2000-2006, the proliferation of specialty centers or organizations providing niche services responding and creating demand for their services was a major factor promoting substantial volume growth for several services reviewed. For spinal injections, sleep studies, and nerve conduction studies, these service-line oriented organizations actively market their services both to the public and to potential referring physicians, contributing powerfully to volume growth for these services, despite the absence of strong clinical evidence supporting such increases. The centers were portrayed as sometimes preferring to focus on the more remunerative tests and procedures than the evaluation and management services that the target populations also need.

A third and related aspect of provider uptake is self-referral, which occurs whenever a provider benefits financially from recommending a particular service to a patient. The concept of self-referral extends from relatively benign examples, such as recommending follow-up visits, to more questionable situations, such as providers having ownership stakes in practices, facilities, or equipment that perform diagnostic tests or procedures. Although there are federal and state legal restrictions on some types of self-referral, there are specific exemptions for referrals within physicians' own practices or facilities as well as in other situations (Casalino, 2008). There is substantial evidence that self-referral is associated with the rapid increase in the utilization of CT/MRI of the brain, CT/MRI of the spine, and cardiac stress testing (Casalino, 2008). For example, growth in utilization by non-radiologists, who order these tests, has far exceeded growth in utilization by radiologists, who do not (Casalino, 2008; Levin, 2008; Levin, 2005). For MRI and CT, there is evidence that many providers exploit loopholes in the self-referral restrictions (Mitchell, 2007). Experts we interviewed indicated that self-referral also plays a role in the rise in less-invasive procedures for BPH due to the opportunity to receive the

facility portion of the Medicare fee when performing the service in their office. For BPH procedures, as with other operations, there has been a shift from hospital outpatient clinics to ambulatory surgery centers and physician offices (Yu, 2008), and the general phenomenon appears driven by physicians' financial stakes in the latter settings (Casalino, 2008).

A fourth dimension of provider uptake was active promotion of new technologies to the specialists by device and pharmaceutical manufacturers. This was a particularly important factor driving the growth of less-invasive procedures for BPH and use of new, portable nerve conduction equipment, according to the experts we interviewed. The manufactures of the relevant devices were active in training providers to perform the procedures, helping them to acquire the equipment, and even in setting up the equipment for each patient being treated.

Fifth, for some services there was a growing belief among providers that the service was a reasonable option for some patients, even in the absence of concrete new evidence. For example, published guidelines sometimes make contradictory recommendations about spinal injections procedures because of the paucity of good studies about their effectiveness. This reflects providers' conflicting clinical perspectives, where proponents rely mostly on clinical experience and positive studies with weaker designs, and skeptics point to a lack of rigorous, definitive studies. At the same time, the contradictory guidelines reinforce the conflicting clinical perspectives, since each group can find a guideline to back-up their views. Similarly, the less-invasive procedures for BPH are new, data are limited, and guidelines and other synthesis of available literature make contradictory recommendations— and yet growth has been enormous. Accordingly, we classified these reasons for growth as "provider uptake," not as new clinical evidence.

C. Financial Factors

Financial factors, encompassing payment rates and coverage decisions, affected eight of the 10 services we reviewed.

Payment Structure: Across the ten services reviewed, experts agreed that reimbursement for technical components of services seemed relatively more lucrative than reimbursement for the evaluation and management (E&M) services that the same physicians perform within their own

specialties and even within other specialties. For example, experts thought that the payment system was much more generous for physicians performing spinal injections for chronic pain than for spending time with patients exploring their psychological reactions to chronic pain or encouraging patients to undertake specific physical training or other self-management approaches. A related issue was that experts in interpretation of nerve conduction studies considered primary care physicians not competent to interpret nerve conduction studies, especially those performed without an accompanying EMG. However, the experts consulted thought the payment system did not compensate physicians adequately for their E&M services and thus the payment for the additional testing served to increase overall payment for evaluating the patients.

Conversely, generous reimbursement under the Medicare fee schedule, particularly for the technical component, was cited as major reasons for the volume growth a number of services. For example, fee growth for BPH procedures gave physician practices incentives to rent or buy the equipment needed to perform the services, a form of self-referral protected under Stark rules.

Table 4 shows the 2000 and 2006 relative values units (RVUs) per service for the major services within the families of codes studied here. Since prices are the product of RVUs and the conversion factor (adjusted for geographic differences in practice expenses), this information provides a sense of relative prices across services, how prices differ by where the services in provided (facility or non-facility) and how prices changed over the study period. Relative prices and their changes varied considerably across the study services. Prices for some services remained fairly stable between 2000 and 2006 (e.g., CTs, MRIs, and nuclear cardiac stress tests), others fell (e.g., defibrillator implantation, eye injections, and ophthalmic imaging), and others increased (e.g., procedures for BPH, electrodiagnostic testing, spinal injections, and polysomnography). The large RVU increases were primarily the result of moving to fully implemented resource-based practice expense RVUs that increased the site of service payment differentials for some services.

Table 4

Change in RVUs per Service for Largest CPT Code within High Growth Service Category

			Non-Facility Total RVU			Non-Facility Practice Expense RVU		
Service Category	**CPT Code**	**Description**	**2000***	**2006**	**% Change**	**2000***	**2006**	**% Change**
Cardiac Defibrillator Implantation to Prevent Sudden Death	33249	Eltrd/insert pace-defib	28.89	23.36	-19.14%	12.87	8.38	-34.89%
Cardiac Stress Testing for Coronary Artery Disease	78465	Heart image (3d), multiple	14.67	14.47	-1.36%	12.63	12.34	-2.30%
CT/MRI Scans of Brain	70450	CT head/brain w/o dye	6.23	6.15	-1.28%	5.13	5.01	-2.34%
	70553	MRI brain w/o & w/ dye	29.86	29.5	-1.21%	26.29	25.73	-2.13%
CT/MRI Scans of Lumbar/Spine	72131	CT lumbar spine w/o dye	7.95	7.83	-1.51%	6.47	6.31	-2.47%
	72148	MRI lumbar spine w/o dye	15.35	15.16	-1.24%	13.26	12.97	-2.19%
Diagnosis and Medication Therapy for Macular Degeneration	67028	Injection eye drug	8.66	5.35	-38.22%	6.04	2.71	-55.13%
	92135	Opthalmic dx imaging	1.93	1.16	-39.90%	1.56	0.79	-49.36%
	92235	Eye exam with photos	2.83	3.51	24.03%	1.94	2.62	35.05%
Electrodiagnostic Testing for Nerve Problems	95904	Sense nerve conduction test	0.86	1.47	70.93%	0.49	1.09	122.45%
Mohs Surgery for Skin Cancer	17304	1 stage Mohs, up to 5 spec	13.4	16.15	20.52%	5.49	8.26	50.46%
Polysomography for Sleep Apnea	95811	Polysomnography w/ cpap	17.38	23.64	36.02%	13.09	19.24	46.98%
Procedures for Benign Prostatic Hyperplasia	53850	Prostatic microwave thermotx	16.83	104.44	520.56%	6.85	94.33	1277.08%
Spinal Injection Procedures for Back Pain	64483	Inj foramen epidural l/s	5.58	9.92	77.78%	3.58	7.91	120.95%

***Transition non-facility RVU**

Although it is not within the scope of this study to estimate the relationship between fee changes and volume growth, the data in Table 4 illustrate several interesting points. First, ICDs and eye injections increased in volume for reasons that were related to new clinical evidence and the provision of these services was not impeded by the fact that fees fell considerably. Second, Mohs surgery and polysomnography were both identified as services that grew, in part, as a result of epidemiological trends. Payment rates for these services were also growing, further stimulating the growth in response to larger pools of patients. Third, fees for electrodiagnostic testing and spinal injections were increasing and this could be a factor in explaining why provider uptake was identified as a cause for rapid growth: providers may have increased the use of these services as a response to profit incentives related to the growth in payment rates. Finally, the extremely large increase in payments for less-invasive BPH procedures may have allowed for the technologically feasible movement of these services out of hospital settings and into physicians offices by paying for the necessary equipment and supplies. Given the increase in non-facility practice expense RVUs, it seems extremely unlikely that this shift in site of service could have occurred without this change in Medicare fees. Literature also supports the view that relatively generous reimbursement for advanced imaging services prior to the Deficit Reduction Act of 2005, which reduced reimbursement for advanced imaging procedures, produced incentives for practices which ordered a lot of advanced imaging services to merge to have sufficient patient volume to support purchase of practice-owned equipment, especially MRIs.

Medicare Coverage Decisions: Physicians' services are generally approved for payment through a standard procedure that does not involve a national coverage decision by CMS. The CPT Editorial process, which is performed under the auspices of the American Medical Association, provides a basic level of evidence review assuring that services for which new CPT codes are sought are used by physicians outside of research or other unique facilities and have some level of support in the medical literature. However, these supporting studies might be uncontrolled or case-controlled studies that lack the rigor generally required for determination of medical effectiveness. Further, the CPT editorial board review does not involve formal health

technology assessment – now called comparative effectiveness - that seeks to determine how a requested new service compares to other services already available.

Medicare has the authority to not pay for new CPT services that have been approved by the CPT editorial panel and given a valuation by the RBRVS Update Committee (RUC). For the most part, CMS has chosen to not cover newly defined E&M services, which arguably can be billed under existing codes. Less commonly, CMS chooses not to pay for new procedures, tests, and imaging procedures that have been given new CPT codes. Part B carriers, now called Medicare Administrative Contractors (MACs), often do establish some limits on payments for new services, e.g. the frequency with which claims for particular services may be paid for. These local carrier decisions vary across the country.

Nevertheless, CMS lacks a systematic approach to deciding which services for which there is a CPT code billed under the Medicare Physician Fee Schedule need to be subjected to formal review in what is called a National Coverage Decision (NCD). An NCD is a determination of whether a service will be covered nationally and if so under what conditions. "Coverage with conditions" can limit the clinical circumstances of patients for which coverage – and payment – is approved. Particular services that enter the NCD process may be identified by providers, manufacturers, disease advocacy groups, CMS staff, or, rarely, Congress. In short, CMS tends to develop NCDs on an as needed, case-by-case basis, in a context in which services that have been given a CPT code are presumably covered unless a formal NCD is requested.

Given this non-systematic approach, it is not surprising that for only two of the services reviewed there was an issue of Medicare coverage. For those two services – ICDs and polysomnography – NCDs were required to consider additional clinical conditions for which coverage would be provided. These specific extensions of coverage indications were essential to permit the large volume growth. In the case of treatment for age-related macular degeneration, however, the large increase in injections with new anti-angiogenic agents occurred based on new clinical data and FDA approval and not new coverage policy from CMS or local contractors. On the other hand, the service that preceded the injections – photodynamic therapy with verteporfin – was subject to controversial coverage decisions.

Discussion

To summarize, we identified ten clinical services for which utilization grew rapidly among Medicare beneficiaries between 2000 and 2006 then used a combination of directed literature reviews and expert interviews to identify one or more major factors influencing the growth of each service. Interestingly, clinical factors and patient demand were factors for eight of the services we studied, but were major factors for only three. New technologies and new scientific evidence stimulated the growth of two services and patient demand drove six. A change in the size of the potentially eligible population was not a major factor for any of the services. Nevertheless, for most services, the potentially eligible population was quite large, setting the stage for rapid growth once other factors came into play. In contrast, financial factors or increased uptake by providers were factors for all ten services and were major factors for seven. Among major financial factors, Medicare coverage decisions influenced two services and reimbursement rates influenced two others. Overall, uptake by providers was the single most important factor, being a major driver of growth for seven services. Provider uptake and financial factors appeared synergistic, such that providers shifted toward providing some services rather than alternatives and established in some cases independent specialty centers, in part to increase revenue.

Which factors were driving growth is a related but slightly different question from *whether* some of the growth may have been *clinically inappropriate*, i.e., whether a service was provided to some patients for whom the associated risks exceeded the potential benefits. For three services, the growth seems appropriate overall. Important new scientific evidence indicates that substantial growth in the use of ICDs for CHF and angiogenesis inhibitors for AMD is warranted. An extremely large reservoir of patients with undiagnosed obstructive sleep apnea suggests that substantial growth in polysomnography would also be warranted. On the other hand, some of the growth in spinal injection procedures and nerve conduction studies appears more likely to be inappropriate, with risks of complications or inaccurate results that exceed clinical benefits for some patients. For the six remaining services whether some of the growth may have been inappropriate remains an open question. However, prior studies suggest that inappropriate use is relatively uncommon (McGlynn, 2003; Fitch, 2001; Shekelle 2001).

Nevertheless, it does seem likely that some of these services offered benefits to patients that were small relative to their cost, i.e., that some of the observed utilization was an *inefficient* use of resources. For example, the potential benefit of routine cardiac stress testing is modest for certain people who have been treated for coronary artery disease in the past but have no symptoms now (ACCF, 2008). Although the potential benefits may exceed the risks associated with doing the test, the money spent on the stress tests might do more to improve length and quality of life if it were spent on tests for symptomatic patients or on cholesterol medications. Medicare is currently barred, however, from taking such considerations into account when making coverage decisions.

Despite that ban, rigorous scientific studies probing the risks and potential benefits of tests and therapies are also needed by front line clinicians as they care for patients. Unfortunately, for many of the ten services, the scientific literature is limited (Neumann, 2008). For example, the less-invasive procedures for BPH have been subjected to only short-term studies, so lack of sustained effect is a major concern (Lourenco, 2008). Mohs surgery is widely accepted as the standard of care for basal cell and squamous cell carcinomas on the face and neck, yet studies demonstrating its effectiveness over wide excision used only non-systematic methods, such as case series. A recent randomized controlled trial calls Mohs effectiveness into question, although it too has limitations (Rowe, 1989; Thissen, 1999; Alam, 2001; Rowe, 1992; Smeets, 2004). Similarly, there is very little high-quality evidence to indicate when injection procedures are most likely to be helpful for patients with chronic low back pain who lack other specific clinical findings, such as presence of neurologic symptoms in the legs.

A lack of adequate evidence to guide medical decision-making has been a problem for decades (IOM, 1985), and there is little reason to believe it will be rectified soon. For example, interviewed experts frequently commented that, whereas pharmaceutical manufacturers are major sponsors of clinical trials of medications, device manufacturers have fewer incentives to sponsor trials and for new procedures there are rarely trial sponsors. The lack of scientific evidence for many health care services and Medicare's permissive coverage policy together permit unfettered uptake by providers and allow factors other than clinical appropriateness to influence when services are provided. The current study's findings illustrate the consequences.

We found that the unfettered uptake of the ten studied services by providers raised some additional, specific policy questions. First, what is the appropriate role of device manufacturers in training and supporting providers in the use of their equipment? Manufacturers have reportedly played a very active role in disseminating the new less-invasive procedures for BPH and ICDs, including training providers in their use. Effectively, this training is marketing. Interestingly, the American Association of Medical Colleges has made a very strong statement against industry involvement in graduate and continuing medical education—yet it specifically exempts training on devices and equipment (AAMC, 2008). Our findings suggest that this practice may warrant closer scrutiny.

Second, should equal reimbursement be provided regardless of the skill or training of the provider? Specialists with expertise in narrow disciplines, such as electrodiagnostic testing, Mohs surgery, and cardiac electrophysiology (ICD implantation) have alleged that providers with nothing more than "a weekend course" of training are performing these services and that this was one major reason for growth. For example, it is a legitimate question whether Medicare should pay equally for a portable electrodiagnostic test performed by a primary care provider as for a standard test by a neurologist or physiatrist.

Third, just as the development of specialty hospitals has been an issue in recent years (MedPAC, 2007), we found that the development of outpatient specialty centers raises some concerns. The active marketing of services to primary care providers and the local community has the potential to continue to drive growth—growth that may not always be appropriate, as in the case of the spinal injection procedures. Further, the incentive for establishing the specialty centers appears to be the ability to capture the practice expense payment. Thus, the fact that these centers appear to be proliferating raises the question as to whether these practice expense payments are more profitable than they need to be.

Fourth, a number of services in on our list of ten had recently seen large increases in their associated number of practice expense RVUs, meaning that the total reimbursement for the service had increased. In the absence of clinical evidence, it is difficult to know whether the prior reimbursement rate led to underprovision or the new one to overprovision, but the experts we interviewed thought it was the latter.

Fifth, the increasing recognition of unnecessary and costly advanced imaging services has spawned a renewal of private health plans reliance on prior authorization, this time targeting advanced imaging services including CT and MRI and some other imaging services (Tynan, 2008; Brock, 2007). CMS is challenged by having to issue coverage decisions that apply broadly, rather than creating prior authorization rules that can adapt to rapidly changing technologies and evidence, and this is a particular problem for imaging (Pearson, 2008). Currently, MACs do have authority to perform medical review – to question quality and medical appropriateness after the fact – so-called "pay and chase." This is likely much less effective than performing prior authorization, selectively for high cost, discretionary, elective services, such as advanced imaging.

Conclusions and Policy Implications

Our results point to the important role that the diffusion of new technology and financial factors play in increasing expenditures for physicians' services – even in the absence of any new clinical evidence or epidemiologic trends. One reason this is the case is that consensus about the appropriate use of most services and procedures simply does not exist, leaving room for other factors to influence care patterns. But determining appropriateness requires rigorous reviews of the clinical evidence, expert panels, or other measures that are usually time- and resource-intensive. In addition, there are potentially a huge number of services that would benefit from examination: it is not simply new technologies that must be reviewed but new and expanded uses of existing technology and services. While over the longer term Congress might appropriate funding for CMS or another government agency to conduct reviews of appropriateness and cost-effectiveness, other methods will be needed to rationalize spending growth in physicians' services over the near term.

Fortunately, our results do point to a number of ways to address potentially inappropriate growth in service use – and ways not to address it. We'll start with what does not appear to be working. Cutting or increasing the payment for all services uniformly, as the SGR policy does, is not producing greater efficiency. Among the ten high-growth services we examined some were clearly delivering high value while others were not. Indeed, we heard repeatedly that declining (relative) payments for E&M services caused by the SGR were partially to blame for

physicians' attempt to make up in procedure volume what they were not compensated for during regular office visits. Second, we cannot rely on existing clinical guidelines to determine what types of volume growth are appropriate. As described above, guidelines are simply not specific enough to translate directly into appropriateness measures, a conclusion that others have also drawn when examining CMS coverage decisions (Appleby, 2008).

Annual review of growing codes. We would, however, recommend implementation of a multi-pronged approach to controlling spending growth, rooted in the methods we piloted in this project. Specifically, the methods developed in this study for identifying high-growth services could be very valuable for targeting reviews and policy changes. While there are over 6000 codes on the CPT schedule, the top 600 account for more than 90 percent of spending and those 600 can be grouped into a much smaller number of code "families." It is reasonable to believe that the top 600 codes could be systematically reviewed on an annual basis.

The annual review of growth in the top codes could incorporate clinical expert advice. We found during this study that that the clinical experts we interviewed were fully capable of absorbing the data presented to them during interviews about growth in service use and reflecting on multiple causes of that growth. Our interviews revealed multiple types of actionable information, such as:

- services for which the RVUs, and especially the practice expense RVUs, might be out of line with true underlying resource costs, making the services relatively profitable;
- intense manufacturer marketing and promotion efforts that signaled over-valued services that were growing for reasons unrelated to concrete evidence of benefit; and
- new technologies being billed and delivered under existing codes that may not provide sufficient benefit.

In addition, the growth in CT/MRIs reinforced the importance of acting on the recommendations of other researchers and government bodies (Mitchell 2007; GAO, 2008; Casalino, 2008; Winter, 2008). All of these findings could be followed-up on and adjustments made to payment rates, billing codes, coverage criteria, or other Medicare policies. With respect to practice expenses,

we would also note that the evidence suggests that they should be reduced in a cost-saving way, rather than the budget-neutral way that RVU changes are currently implemented.

Systemic changes to address growth. Moreover, there are a few ways in which CMS could begin to address more systematic problems with physicians' services growth. First, we were repeatedly told that the payment differentials between E&M services on the one hand and tests and procedures on the other were contributing to inefficient practice patterns. Although the principle behind the RBRVS system of reimbursing at the level of the average costs of each service is admirable, failure to estimate average prices correctly is clearly having perverse effects. E&M rates are not keeping up with new technologies that are being added to the fee schedule. They should be increased so that providers' incentives to over-utilize tests and procedures to increase revenue are mitigated and so that managing chronic diseases becomes more remunerative. Of course, this also means that fees for over-valued tests and procedures must be reduced – otherwise there is a risk that volume growth in both areas will continue. Second, CMS should seek the authority to augment the local medical review procedures conducted by the MACs. These procedures could include the types of prior authorization activities that private insurers are implementing to limit technology use to indications for which it has been proven to be effective. Consistent with other efforts that CMS is considering, such as case management payments for "medical homes," payments for episodes of care, and incentive payments for achieving cost and quality targets, these measures would move the Medicare program in the direction of rewarding value, rather than simply reimbursing costs. Over the long term, this is the only way for the program to break out of the cycle of constantly adjusting thousands of individual service prices in an attempt to align providers' incentives with those of the country as a whole.

Future Research

There are any number of interesting issues raised by this study that could be usefully pursued in further work. A few bear special mention. We singled out codes for which expenditures were high and growing: we might have done even better to single out codes that growing unevenly across the county. It is well known that Medicare costs vary dramatically from region to region, often without any difference in patient outcomes. Services which grew

rapidly in one area but not another might be those for which the evidence base is weaker, and the arguments for limiting growth commensurately stronger.

Similarly, little is known systematically about the review policies and effectiveness of Medicare's MACs and how they compare to approaches private insurers, including the same ones that serve as MACs, implement for private customers (Foote, 2004). We could learn what private insurance carriers are doing to limit overuse, especially of imaging services and diagnostic tests, and whether these approaches are applicable in Medicare.

In addition, given the interest in using results from this type of study to assist in the reform of the SGR, it would be important to develop better estimates of the relationship between Medicare fee changes and volume growth at the service level. The literature on the relationship between physician fees and volume has grown out of interest in exploring the phenomenon of supplier induced demand (e.g., McGuire and Pauly, 1991). However, evidence of inducement is weak when focused on specific CPT codes as opposed to broad categories of services (e.g., Mitchell, Hadley and Gaskin, 2000 and 2002; Jacobson et al., 2006). It would be useful to carefully design a study of the effects of the "natural experiments" produced by the recent fee changes for several of the services considered here.

Finally, we could conduct some example studies to demonstrate the types of methods that might inform future coverage decisions, or be used to revise existing coverage decisions. One candidate would be a claims-based analysis of the episode costs of treating BPH with different modalities; another would be an appropriateness panel on spinal injections for different groups. These studies would not only be useful in their own right, but would allow for discussion and debate about the consideration of costs and the use of appropriateness panels.

References

AAMC (2008): Industry Funding of Medical Education. (Last accessed on December 10, 2008) https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114

ACCF/ASE/ACEP/AHA/ASNC/SCAI/SCCT/SCMR (2008): Appropriateness Criteria for Stress Echocardiography; 117; 1478-1497; http://circ.ahajournals.org/cgi/content/full/117/11/1478

Alam M, Ratner D. (2001) Cutaneous Squamous-Cell Carcinoma. *New England Journal of Medicine*; 344(13):975-83.

Appleby, Julie (2008): The Case of CT Angiography: How Americans View and Embrace New Technology *Health Affairs*, 27(6); 1515-1521.

Brock, A. (2007): Medical Imaging: Equipment and Related Products" (Wellesley, Mass: BCC Research, October 2007).

Casalino LP. (2008) The Synthesis Project: Physician Self-referral and Physician-owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No. 15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf

(CBO) Congressional Budget Office (2007) *Factors Underlying the Growth in Medicare's Spending for Physicians' Services*, Congressional Budget Office Background Paper, June (2007). http://www.cbo.gov/ftpdocs/81xx/doc8193/06-06-MedicareSpending.pdf

CDC Obesity Trends (Last accessed on December 10, 2008) http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/

Ceilley RI, Del Rosso JQ. (2006) Current Odalities and New Advances in the Treatment of Basal Cell Carcinoma. Internationa Journal of Dermatology; 45(5):489-98.

Fitch K, Bernstein SJ, Aguilar MD, et al. (2001) The RAND/UCLA Appropriateness Method User's Manual. Santa Monica, CA: RAND Corporation; MR-1269-DG-XII/RE.

Foote, S.B., D. Wholey, T. Rockwood, & R. Halpern. (2004) Resolving the Tug-of-War Between Medicare's National and Local Coverage, *Health Affairs;* 23(4):108-123.

Government Accountability Office, Medicare: Trends in Fees, Utilization, and Expenditures for Imaging Services before and after Implementation of the Deficit Reduction Act of 2005 (2008) GAO-08-1102R September 26, 2008 http://www.gao.gov/docsearch/app_processform.php

(IOM) Institutes of Medicine. (1985): Committee for Evaluating Medical Technologies in Clinical Use. Assessing Medical Technologies. Washington, DC: National Academy Press.

Jacobson M, O'Malley AJ, Earle CC, Pakes J, Gaccione P, Newhouse J, (2006) Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients? *Health Affairs* 25(2):437-443.

Kaiser Family Foundation (2008) Kaiser Daily Health Policy Report (Last accessed on December 10, 2008) http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=51513

Klein R, Klein BE, Linton KL. (1992) Prevalence of Age-Related Maculopathy: the Beaver Dam Eye Study. *Ophthalmology*;99:933-43.

Levin DC, Intenzo CM, Rao VM, Frangos AJ, Parker L, Sunshine JH. (2005) Comparison of Recent Utilization Trends in Radionuclide Myocardial Perfusion Imaging among Radiologists and Cardiologists. *Journal of the American College of Radiology*; 2(10):821-4.

Levin D, Rao VM, Parker L et al. (2008) Ownership or Leasing of MRI Facilities by Nonradiologist Physicians is a Rapidly Growing Trend. *Journal of the American College of Radiology*; 5: 105-109.

Lourenco, Tania. et al. (2008) Alternative Approaches to Endoscopic Ablation for Benign Enlargement of the Prostate: Systematic Review of Randomised Controlled Trials. *British Medical Journal* 337; a449.

Maxwell, Stephanie, Stephen Zuckerman and Robert Berenson, (2007) Use of Physicians' Services under Medicare's Resource-based Payments *New England Journal of Medicine* 56(18): 1853-61.

McClellan, Mark B (2005). Medicare Coverage of ICDs. New England Journal of Medicine 352;3.

McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. (2003) The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine;* 348(26):2635-45.

McGuire, T. and M. Pauly. (1991). Physician Response to Fee Changes with Multiple Payers. *Journal of Health Economics*. 10, 385–410.

(MedPAC) Medicare Payment Advisory Commission, (2007) *Assessing Alternatives to the Sustainable Growth Rate System*, Washington, DC http://medpac.gov/documents/Mar07_SGR_mandated_report.pdf

Mitchell JM. (2007) The Prevalence of Physician Self-Referral Arrangements after Stark II: Evidence from Advanced Diagnostic Imaging. *Health Affairs Web Exclusive;* 26: w415-w424.

Mitchell JM, Hadley J, Gaskin DJ, (2000) Physicians' Responses To Medicare Fee Schedule Reductions. *Medical Care.* 38(10):1029-39.

Mitchell, JM, Hadley J, Gaskin DJ. (2002). Spillover Effects of Medicare Fee Reductions: Evidence From Ophthalmology. *International Journal of Health Care Finance and Economics*. 2(3):171-88.

Neumann, P., M. S. Kamae, and J. A. Palmer, (2008) Medicare's National Coverage Decisions for Technologies, 1999–2007, *Health Affairs;* 27(6):1620–31.

Pearson, Steven D. et al. (2008): "Accessing the Comparative Effectiveness of a Diagnostic Technology: CT Colonography" Health Affairs, 27(6); 1503-1514.

Rowe DE, Carroll RJ, Day CL Jr. (1989) Long-term Recurrence Rates in Previously Untreated (primary) Basal Cell Carcinoma: Implications for Patient Follow-up. *Journal of Dermatologic Surgery and Oncology*; 15:315–328.

Rowe DE, Carroll RJ, Day CL Jr. (1992) Prognostic Factors for Local Recurrence, Metastasis, and SurvivalRates in Squamous Cell Carcinoma of the Skin, Ear, and Lip: Implications for Treatment Modality Selection. Journal of the American Academy of Dermatology; 26:976-90.

SEER (2008) LAG, Melbert D, Krapcho M, Stinchcomb DG, Howlader N, Horner MJ, Mariotto A, Miller BA, Feuer EJ, Altekruse SF, Lewis DR, Clegg L, Eisner MP, Reichman M, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2005, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2005/ , based on November 2007 SEER data submission, posted to the SEER web site, http://seer.cancer.gov/csr/1975_2005/index.html

Shekelle PG, Park RE, Kahan JP, Leape LL, Kamberg CJ, Bernstein SJ. (2001) Sensitivity and Specificity of the RAND/UCLA Appropriateness Method to Identify the Overuse and Underuse of Coronary Revascularization and Hysterectomy. *Journal of Clinical Epidemiology*.; 54(10):1004-10.

Smeets NWJ, Krekels GAM, Ostertag JU, Essers BAB, Dirksen CD, Nieman FHM, et al. (2004) Surgical Excision verses Mohs' Micrographic Surgery for Basal-cell Carcinoma of the Face: Randomised Controlled Trial. *The Lancet*; 364:1766–72.

Thissen M et al. (1999) A Systematic Review of Treatment Modalities for Primary Basal Cell Carcinomas. Archives of Dermatology 135: 1177–1183.

Tynan A, Berenson RA, and Christianson JB. (2008) Health Plans Target Advanced Imaging Services: Cost, Quality, and Safety Concerns Prompt Renewed Oversight. Center for Studying Health System Change, Issue Brief #118.

Winter A and Ray N. (2008): Paying Accurately for Imaging Services in Medicare.*Health Affairs*; 27(6):1479-1490.

Young T. (2002) Epidemiology of Obstructive Sleep Apnea: A population health perspective. *American Journal of Respiratory Critical Care Medicine* Vol 165. pp 1217–1239.

Yu X, Elliott SP, Wilt TJ, McBean AM.(2008) Practice Patterns in Benign Prostatic Hyperplasia Surgical Therapy: The Dramatic Increase in Minimally Invasive Technologies. *Journal of Urology*; 180(1):241-5.

Appendix I

Cardiac Defibrillator Implantation to Prevent Sudden Death

1. Background on Service:

A. Condition(s) Associated with the Service:

Sudden cardiac death (SCD) has been defined as unexpected death from a cardiac cause occurring within a short time, generally within 1 hour of symptom onset. Medicare beneficiaries currently account for 80% of the cases of SCD in the United States (McClellan, 2005). Most cases (85%) occur when ventricular tachycardia (VT) or ventricular fibrillation (VF) develops. Major risk factors for SCD include: (1) a previous history of resuscitated cardiac arrest or persistent VT/VF, (2) cardiomyopathy (particularly with reduced ejection fraction)[*], and (3) coronary artery disease (CAD). CAD causes about 75% to 80% of SCD, often shortly after a heart attack or because one or more heart attacks lead to "ischemic" cardiomyopathy over time. SCD also affects patients with non-ischemic cardiomyopathy or other disorders (Sukhija, 2007).

B. Description of Service:

An implantable cardioverter defibrillator (ICD) is a device consisting of a programmable pulse generator unit (generally implanted in the upper chest) and one or more leads for defibrillation electrodes (generally positioned inside the right heart). The leads continuously sense the cardiac rhythm and the programmable unit analyzes the rhythm. When the unit detects VT or VF, the device delivers electrical shocks to the ventricle via the leads, hopefully restoring normal rhythm. Newer devices provide additional functions, such as pacing, if bradycardia occurs (DiMarco, 2003).

[*] Cardiomyopathy means disease of the heart muscle. Ejection fraction means the percentage of blood in the heart that is ejected into the aorta during a single heart beat. An ejection fraction is normal if it is above 50%. Ischemic cardiomyopathy is caused by CAD (Wilson, 2007).

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

Charges per beneficiary for the insertion of implantable cardiac defibrillators with or without pacing functions (CPT 33249) grew from $0.70 to $1.90 (170.86%) between 2000 and 2006. The analysis of pacer/defibrillator units (CPT 93744), a follow-up service used to assess the settings, function, and activity of the units, grew from $0.03 to $0.52 (1,776.21%).

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: The Medicare population is aging, with the very old (over age 85) making up an increasing proportion. However, population changes between 2000 and 2006 were very modest, which means it does not explain the substantial growth in the use of this service (U.S. Census Bureau, 2008). CAD is very prevalent among older patients. Non-ischemic cardiomyopathy has a variety of causes, many of which also become more common with advancing age (Wilson, 2007).

Better Evidence of Benefit or Benefit to New Types of Patients: ICDs were initially used as secondary prevention among in patients with a history of SCD (and successful resuscitation), or refractory VT or VF. (DiMarco, 2003; ACC Devices, 2008). Following a series of clinical trials published in the late 1990s to early 2000s, ICDs have become recommended as primary prevention for patients with ischemic and non-ischemic cardiomyopathy with reduced ejection fraction. Primary prevention means use in patients who are at risk for but have not yet had experienced sustained VT, VF, or resuscitated cardiac arrest (ACC devices, 2008). These trials first focused on patients with ischemic cardiomyopathy and later demonstrated that the benefit is similar among patients with non-ischemic cardiomyopathy. A 2007 Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center report reviewing available clinical trials concluded that ICDs are “efficacious and effective when added to optimal medical

therapy in patients with left ventricular ejection fraction <35%, regardless of whether they have [heart failure] symptoms." The report found that ICDs reduced all-cause mortality in patients with left ventricular systolic dysfunction by 20%, with a 54% reduction in sudden cardiac deaths (McAlister, 2007). Much of the growth in ICD utilization has been among patients with heart failure (3% of ICD utilization in 2000 vs. 44% in 2006, in our analysis of Medicare claims data).

The appropriateness of ICDs does not only depend on their effects on mortality but also on factors such as which patient subgroups are most likely to benefit, which devices are most appropriate, the risks of implantation outside the highly controlled clinical trial setting, the effects of ICDs on quality of life, the role of life expectancy, and concerns about the management of ICDs after patients develop terminal illnesses. Future research on the outcomes of patients with ICDs will help to clarify these issues, and elucidate exactly when they are appropriate or inappropriate (Lewis, 2006; ACC Devices, 2008). A final factor pertaining to the possibility of inappropriate use is that the patients' symptoms are important to determining whether ICDs are indicated or not, and symptom classification is a subjective assessment by cardiologists.

New Technology: Devices that combine an ICD function with a feature that resynchronizes the contraction of the two ventricles have emerged recently as a treatment for patients with heart failure (Bristow, 2004). However, the incremental benefit of resynchronization-ICDs over ICDs alone is uncertain (McAlister, 2007). Combined devices do not appear to be a major driver of utilization during the 2000 to 2006 period, but may grow in the future.

B. Diffusion:

Patient Demand: Public awareness of ICDs might have increased, given it is widely known that the Vice President Dick Cheney has one; however, this seems unlikely to be even a moderate contributor to the rate of observed growth.

Provider Uptake: There appears to be a substantial underutilization of ICDs among patients for whom there is strong evidence of benefit (ACC Devices, 2008).

Manufacturers of ICDs have reportedly played an active and important role in disseminating the use of this service. In addition to advertising, some have been involved in training providers to implant ICDs, working with physician groups to identify patients who may be candidates, and even assisting physicians with implementation. Some trainings reportedly consist of courses that last no more than a few days. Many of the people undergoing these trainings are not electrophysiologists, some are not cardiologists, and 15% have no formal training whatsoever beyond these abbreviated courses (ACC Devices, 2008).

As with cardiac stress testing, the fact that cardiologists both recommend and implant ICDs creates a potential for self-referral (Casalino, 2008). Interviewed experts expressed concern that self-referral incentives may be stimulating utilization.

C. Financial Factors:

Payment Structure: The reimbursement for this procedure is reportedly good, particularly relative to Evaluation and Management services, and this might be contributing to growth.

Medicare Coverage Decisions: Major coverage changes occurred in 2003 and 2004. Before that point, Medicare covered ICDs for secondary prevention only. In 2003, Medicare expanded coverage to include primary prevention of SCD for patients at high risk due to ischemic cardiomyopathy. In 2004, coverage for ICDs was extended to patients with non-ischemic cardiomyopathy and an ejection fraction of 35% or less. These major expansions were in direct response new literature and were expected to triple the number of patients who would be eligible for ICDs, increasing the population to 500,000 (McClellan, 2005).

To determine whether the changes in the utilization of this service are consistent with the changes in the new clinical evidence coverage decisions, we examined the proportion of ICD insertions associated with and growth in utilization has primarily occurred among patients with heart failure. According to the Relative Value Update Committee (RUC) database, in 2001 and 2002, 21,000 and 26,000 ICDs were implanted respectively. In 2003, the number started to increase, reaching 74,000 in 2006. Between 2003 and 2006, a total of 273,000 ICDs were implanted (RBRVS Data Manager, 2008); assuming roughly 25,000 per year implanted for indications other than heart failure, approximately 173,000 were implanted for heart failure by 2006, a fraction of the 500,000 that Medicare anticipated.

4. Summary:

The growth in the use of ICDs appears substantially explained by the development of evidence showing benefit to new groups of patients, and the translation of this evidence into Medicare coverage decisions. Because the expansion in the use of this service is relatively new and additional evidence is being developed, the subgroups of patients who benefit most are still being clarified. The rise in utilization that we observed is actually well below the size of the population that would benefit from ICDs.

Section References:

(ACC Devices) 2008 Guidelines Device for Device-Based Therapy of Cardiac Rhythm Abnormalities. (2008) *Journal of the American College of Cardiology*; 51;e1-e62

Bristow MR, Saxon LA, Boehmer J, Krueger S, et al; (2004) Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Investigators. Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure. *New England Journal of Medicine;* 350(21):2140-50.

Casalino LP. (2008) The Synthesis Project: Physician Self-referral and Physician-owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No. 15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf

DiMarco JP, (2003) Implantable Cardioverter-Defibrillators, *New England Journal of Medicine;* 349:19

Lewis WR, Luebke DL, Johnson NJ, Harrington MD, Costantini O, Aulisio MP. (2006) Withdrawing Implantable Defibrillator Shock Therapy in Terminally Ill Patients. *American Journal of Medicine* ;119:892– 6.

McAlister FA, Ezekowitz J, Dryden DM, Hooton N, Vandermeer B, Friesen C, Spooner C, Rowe BH. (2007) Cardiac Resynchronization Therapy and Implantable Cardiac Defibrillators in Left Ventricular Systolic Dysfunction. Evidence Report/Technology Assessment No. 152 (Prepared by the University of Alberta Evidence-based Practice Center under Contract No. 290-02-0023). AHRQ Publication No. 07-E009. Rockville, MD: Agency for Healthcare Research and Quality. June 2007.

McClellan, Mark B (2005) Medicare Coverage of ICDs. *New England Journal of Medicine*; 352;3

Sukhija, Rishi, Vimal Mehta, Marino Leonardi, Jawahar L. Mehta. (2007) Implantable Cardioverter Defibrillators for Prevention of Sudden Cardiac Death. *Clinical Cardiology* (1)30, 3-8

RBRVS Data Manager CD (2008) from the American Medical Association

U.S. Census Bureau (2008) Population Projections (Last accessed December 10, 2008) http://www.census.gov/population/www/projections/usinterimproj/

Wilson. (2007) In the Clinic: Heart Attacks. *Annals of Internal Medicine*. http://www.annals.org/cgi/reprint/147/11/ITC12-1.pdf

Appendix II

Cardiac Stress Testing for Coronary Artery Disease

1. Background on Service:

A. Condition(s) Associated with the Service:

Coronary artery disease (CAD) is a build-up of cholesterol-rich plaque inside the arteries that supply the cardiac muscle. These plaques can limit blood flow and this can cause chest pain and other symptoms. When plaques rupture, clots can form and cause heart attacks. CAD is a leading cause of death in Medicare population (CDC, 2005). The prevalence of CAD in the Medicare age group is high: between 1999 and 2004, 15-23% of those age 60 to 79, and 22-33% of those age 80 and above had the condition (American Heart Association, 2008).

B. Description of Service:

Cardiac stress testing detects reduced blood flow to cardiac muscle. There are three commonly used ways of assessing reduced blood flow: electrocardiography ("EKG"); echocardiography, which assesses heart muscle movement; and nuclear medicine studies, which detect the uptake of radioactive tracer from the blood by the cardiac muscle. During testing, these three ways of assessing blood flow are applied at baseline and then after some "stress" on the heart. Two types of "stress" involve stimulating the heart to beat harder through exercise or the administration of medication. An alternative is to give patients a medication that dilates the coronary arteries, then assess whether there is a resulting increase in radioactive tracer uptake by the heart muscle on radionuclide imaging.

These tests are done to diagnose heart attacks and CAD, assess prognosis, and determine the appropriate course of treatment, including determining which patients should undergo coronary

angiography. Current guidelines recommend exercise-based stress testing with electrocardiography and without imaging as the initial test for selected patients; however, this can be inaccurate in many people. Therefore, echocardiography or nuclear imaging studies are performed instead. Stress echocardiography and nuclear testing are nearly equivalent in their ability to diagnose CAD, and, with rare exceptions, are virtually interchangeable (ACC/AHA, 2003; ACC/AHA2, 2003; ACC/AHA, 2002; Kim, 2001).

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

Charges per beneficiary for electrocardiographic stress testing (CPT 93015) grew from $4.99 in 2000 to $7.26 in 2006 (45.6%). Stress echocardiography (CPT 93350) charges grew from $1.26 to $1.66 (31.5%). Charges for the basic nuclear medicine test (CPT 78465) grew from $15.92 to $34.90 (119.3%).[†]

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: The Medicare population is aging, with the very old (over age 85) making up an increasing proportion. However, population changes between 2000 and 2006 were very modest, which means it does not explain the substantial growth in the use of these services (U.S. Census Bureau, 2008).

It is possible that the use of stress tests is changing in response to changes in other clinical practices, such as a growth in cardiac observation units in emergency departments or an increase in the rate of major surgeries for which pre-operative stress testing may be needed.

[†] We report growth for high-utilization CPT codes. A more complete list of codes would be: stress echocardiography (93350), exercise treadmill or pharmacological stress test (93015, 93016-93018), and myocardial nuclear imaging (78460-78461, 78464-78466, 78468-78469, 78472-78473, 78478, 78480-78481, 78483, 78491-78492, 78494, 78496) (Lin, 2008)

Better Evidence of Benefit or Benefit to New Types of Patients: Through our review of key literature and interviews with cardiologists, we did not identify any major new studies or guideline changes showing that stress testing is more beneficial than previously believed, or that it may be useful in more clinical situations. Nor is there any new information to suggest that nuclear medicine stress tests are preferable to echocardiographic ones.

One recent study demonstrated that stress testing is actually underused before coronary angiography (Lin, 2008). Despite this, there is also a possibility that stress testing is sometimes being performed in inappropriate or marginal clinical situations. The American College of Cardiology/American Heart Association has recently developed a set of appropriateness indicators for echocardiography (ACC/AHA2, 2003), and a comparable set for nuclear medicine testing is in the final stages of development (ACC/AHA, 2003). These indicators would make it possible for future research to determine the actual contribution of inappropriate tests to the overall growth in the use of this service.

New Technology: Not applicable.

B. Diffusion:

Patient Demand: We found no evidence of change.

Provider Uptake: An aspect of provider uptake of particular interest is "self-referral," meaning cardiologists referring patients for stress tests performed in a facility in which the cardiologist has an ownership stake or other financial interest (Casalino, 2008). Although federal and state laws restrict some forms of self-referral, they specifically permit self-referral within a provider's office or practice group (Mitchell, 2007). Many cardiologists have nuclear medicine or echocardiographic facilities within their offices, and the ability to self-refer is associated with rapid growth in utilization. One study examining myocardial perfusion scanning by radiologists

vs. cardiologists between 1998 and 2002 found a 2% growth in studies performed by radiologists and 78% growth in studies performed by cardiologists. Most of the utilization by cardiologists occurred in office-based facilities, where the growth rate was 101% (Levin, 2005). We also observed growth in utilization by cardiologists between 2000 and 2006: in 2000, cardiologists performed 58% of nuclear stress tests compared with 71% in 2006.

A factor that may partly explain the greater use of nuclear over echocardiographic stress testing is that it is easier for cardiologists to acquire the expertise needed to independently perform nuclear tests. Being competent to independently perform nuclear stress testing requires only four months of training. In contrast, becoming certified to independently perform echocardiographic stress tests requires at least 12 months of specialized training, including several months of additional training after a standard cardiology fellowship are generally needed (ACCF COCATS 3, 2008).

C. Financial Factors:

Payment Structure: Additional research may be needed to examine the profit margin for nuclear medicine vs. echocardiographic stress tests because interviewed experts indicated that nuclear testing is generally perceived as quite profitable. Stress echocardiography (CPT 93350) is currently associated with 4.00 relative value units (RVUs) (including the physician and physician-office components), representing a 33% increase from 2000 to 2006. The basic nuclear medicine test (CPT 78465) is associated with a higher level: 14.47 RVUs (including physician and office component), and these have remained relatively flat during the study period (AMA, 2008). A recent analysis of reimbursements for imaging services including nuclear medicine and echocardiographic studies indicates that both may be over-reimbursed overall, particularly in high-cost markets (Winter, 2008).

Medicare Coverage Decisions: We identified no relevant Medicare coverage decisions within the time frame of these utilization trends.

4. Summary:

It appears that clinical factors probably have not produced the substantial growth in the use of cardiac stress testing among Medicare beneficiaries, particularly the differential growth of nuclear vs. echocardiographic testing. Financial factors, including legal forms of self-referral within practices, appear to have been more important. The appropriateness of RVUs, particularly the office facility component, and the appropriateness of the tests themselves should be examined in greater detail.

Section References:

ACC/AHA (2002) Guideline Update for Exercise Testing (Last accessed December 10, 2008)http://www.acc.org/qualityandscience/clinical/guidelines/exercise/exercise_clean.pdf

ACC/AHA (2003) Guideline for the Clinical Use of Cardiac Radionuclide Imaging (Last accessed December 10, 2008) http://www.acc.org/qualityandscience/clinical/guidelines/radio/index.pdf

ACC/AHA2 (2003) Guideline Update of the Clinical Application of Echocardiography (Last accessed December 10, 2008) http://www.acc.org/qualityandscience/clinical/guidelines/echo/index_clean.pdf

ACCF COCATS 3 (2008) Training Statement Featuring: Task Force 4: Training in Echocardiography, Endorsed by the American Society of Echocardiography: http://www.asefiles.org/COCATS.pdf

(AMA) (2008) American Medical Association website: CPT Search (Last accessed December 10, 2008) https://catalog.ama-assn.org/Catalog/cpt/cpt_search.jsp

American Heart Association (2008) Heart Disease and Stroke: Statistics (Last accessed December 10, 2008) http://www.americanheart.org/downloadable/heart/1200082005246HS_Stats%202008.final.pdf

Casalino LP. (2008) The Synthesis Project: Physician Self-referral and Physician-owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No.

15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf.

CDC (2005) National Vital Statistics Reports, 2005. (Last accessed December 10, 2008). http://www.cdc.gov/nchs/data/nvsr/nvsr56/nvsr56_10.pdf

Kim C, Kwok YS, Heagerty P, Redberg R. (2001) Pharmacologic Stress Testing for Coronary Disease Diagnosis: A Meta-Analysis. *American Heart Journal*; 142(6):934-44.

Levin DC, Intenzo CM, Rao VM, Frangos AJ, Parker L, Sunshine JH. (2005) Comparison of Recent Utilization Trends in Radionuclide Myocardial Perfusion Imaging among Radiologists and Cardiologists. *Journal of the American College of Radiology*; 2(10):821-4.

Lin GA, Dudley RA, Lucas FL, Malenka DJ, Vittinghoff E, Redberg RF. (2008) Frequency of Stress Testing to Document Ischemia Prior to Elective Percutaneous Coronary Intervention. *Journal of the American Medical Association*; 300(15):1765-1773.

Mitchell JM. (2007) The Prevalence of Physician Self-Referral Arrangements after Stark II: Evidence from Advanced Diagnostic Imaging. *Health Affairs* 26(3):w415-24.

U.S. Census Bureau (2008) Population Projections (Last accessed December 10, 2008) http://www.census.gov/population/www/projections/usinterimproj/

Winter A, Ray N. (2008) Paying Accurately for Imaging Services in Medicare. *Health Affairs*; 27(6):1479-90.

Appendix III

CT/MRI Scans of the Brain

1. Background On Service

A .Condition Associated with the Service

There are many conditions related to the head and brain for which standard computed tomography (CT) and/or magnetic resonance imaging (MRI) scans are performed. Practice guidelines developed by the American College of Radiology, for example, have identified 23 primary indications and 11 extended indications for MRI of the brain. (ACR Guideline, 2008) Further, many of these problems are quite common in the Medicare population. Common diagnoses include seizures; headache; dementia; various vascular conditions; strokes from infarctions and bleeds; subdural hematomas (often resulting from trauma); benign and malignant brain tumors and metastases, and neurodegenerative conditions such as Parkinson's disease. Evaluation of Medicare claims shows that no condition dominates. For example, for current procedural terminology (CPT) code 70450 "CT scan without contrast," 12.5% of the claims identified "acute cerebrovascular disease" as the primary diagnosis, 12% were for "headache, including migraine," and 10% were for "other injuries and conditions due to external causes." Five other conditions were represented in more than 5% of the cases. There was a similar broad distribution for the other CT codes and the MRI codes, although the specific diagnoses varied to some extent.

B. Description of Services

Computed tomography (CT) is a diagnostic tool that uses special x-ray equipment to obtain data from different angles around the body, then uses computer processing of the information to show

a cross-section of body tissues and organs. Although historically the images generated were in the axial or transverse plane, modern scanners allow this volume of data to be reformatted in various planes or even as volumetric (3D) representations of structures.

Magnetic resonance imaging (MRI) is a diagnostic technique that uses cylindrical magnetic and radio waves to produce high quality multi-planar images of organs and structures within the body without x-rays or radiation. The body's hydrogen atoms react to the magnetic field and pulses of radio waves. This reaction is then changed to an image by computer.

Both CT and MRI scanners can generate multiple two-dimensional cross-sections (slices) of tissue and three-dimensional reconstructions. Unlike CT, which uses only X-ray attenuation to generate image contrast, MRI has a long list of properties that may be used to generate image contrast. By variation of scanning parameters, tissue contrast can be altered and enhanced in various ways to detect different features.

Generally, the MRI is preferred when for examining soft tissues in addition to bone. The CT requires less time than an MRI and can be more readily performed in acute care settings, such as in emergency departments.

MRI equipment is expensive, CTS scans are less so.

2. Observed Growth from 2000 to 2006

Six CPT codes represent the various permutations of use of CT and MRI with regard to the use of contrast material, that is, "without contrast," "with contrast," and "without contrast, followed by with contrast." For all six codes combined, there was a 56% growth in allowed charges between 2000 and 2006. However, there was disproportionately high growth in the most complex MRI scan – 70553, the scan without and with contrast. This service increased 89%. The second fastest growth was in CT without contrast, which grew 57%. There were reductions in

use of the other two CT scans of the brain. Overall, there was a small shift in the proportion of the total of CT and MRIs that were MRI scans, increasing from 66% in 2000 to 70% in 2006.

3. Potential Reasons for Growth

A. Clinical Factors:

Epidemiologic Trends: An aging population would increase the prevalence of cerebrovascular disease and other degenerative brain diseases associated with aging and therefore produce a small trend toward increased volume between 2000 and 2006.

Better Evidence of Benefit or Benefit to New Types of Patients: There have not been important new clinical indications for the traditional CT and MRI scans. There have been new modifications in scanning technology for additional indications including CT and MR angiography, which provides an enhanced approach to detect vascular disease; however, there are specific new CPT codes for computed tomographic angiography (CTA) and magnetic resonance angiography (MRA), which are not considered here. At the same time, there has been ongoing improvement in the CT and MR scanning technologies used to enhance the images produced, such as diffusion-weighted imaging and perfusion-weighted imaging. However, these quality enhancements, which are not supported with new CPT codes or additional payments, have not changed the basic clinical indications for the service. They may, however, produce a higher quality scan.

In recent years there has been an increasing recognition of unnecessary and costly advanced imaging services. This has spawned a renewal of private health plans reliance on prior authorization, this time targeting advanced imaging services including CT and MRI and some other imaging services. (Tynan, 2008)

The American College of Radiology (ACR) has produced clinical practice guidelines for a number of clinical conditions for which advanced imaging of the brain might be indicated. For each they provide an appropriateness rating on a nine point scale of specific imaging procedures with 9 being "most appropriate" and 1 "least appropriate." For "probable Alzheimer's disease (AD)" MRI without contrast is rated highest at 8/9. For "possible Alzheimer's disease," both MRI without contrast and MRI without and with contrast receive 8/9 appropriateness scores (ACR Appropriateness Criteria, 2007). The summary of this guideline's literature review concludes that MRI is indicated "to exclude other intracranial disorders that might cause dementia," and further that "patients with possible AD have a greater incidence of other significant intracranial pathologies detected on neuroimaging studies than patients with probable AD," based on clinical evaluation. Yet, both clinical situations generated an 8/9 score suggesting that CT and MRI have become standard and recommended in these guidelines to exclude unanticipated conditions, rather than to positively confirm diagnoses. Experts we interviewed agreed with these recommendations. "To exclude other conditions" is a similar rationale for use of CT and MRI in many clinical circumstances described in ACR's dementia guidelines.

For another example, "Worsened chronic headache - History of headache," ACR gives various CT and MRI interventions only 4/9 ratings, whereas for "Sudden onset of severe headache," ACR rates CT, without contrast as a 9/9 in appropriateness. Given the wide variety of conditions and specific clinical situations for which guidelines have or could be developed, it impossible to provide a simple conclusion about whether these interventions are being appropriately performed (ACR Guidelines, 2006). The data available from claims generally does not provide the level of clinical detail needed to assess overuse of these imaging services.

New Technology: Not applicable.

B. Diffusion

Patient Demand: Experts thought that patients have become very aware of advanced imaging services, partly stimulated by direct-to-consumer advertising. For example, patients may be aware of less confining MRI scanners that are open on all sides and purportedly produce less patient anxiety related to spending a long time in a confined space. Accordingly, even when there may be no good clinical indication for the scan, patients, now aware of these technologies, may seek reassurance and request the non-invasive scan.

Provider Uptake: Experts also thought that "defensive medicine" related to the threat of malpractice suits was a contributing factor to ongoing pressure for performance of advanced imaging, especially of the brain. A particular form of defensive medicine occurs in relation to advanced imaging from emergency departments. A number of factors are cited: the pressure of growing emergency department (ED) volume with decreased time to do thorough evaluations; the increasing reliance in EDs on generalists, including non-physicians such as nurse practitioners, who may lack of confidence in their clinical skills and thus have a low threshold for ordering advanced imaging scans; and the increasing perspective adopted by ED personnel that many patients in the ED do not have a usual source of care and therefore need more definitive workups rather than mere screening and stabilization (as required under the Emergency Medical Treatment and Active Labor Act (EMTALA)). These factors lead to almost automatic referral for CT from the ED for care of patients presenting with virtually any condition for which an advanced imaging study might ever be indicated and on all patients whether or not they have a reliable source of ongoing care.

In addition, experts thought that the broader availability of scans and resulting absence of long waits for non-emergency scans was contributing to greater ordering by a range of physicians and non-physicians. Experts thought that even more than ever, physicians feel professional pressure to not miss a diagnosis especially since the consequences, e.g. brain tumor in a patient with headaches, or subdural hematoma in a patient with progressive dementia, are so significant. One expert thought that in many cases the precision of the advanced imaging scan was such that it was even replacing the basic clinical workup provided by a detailed history and physical – a

costly advance but understandable given the power of the technology. Primary care physicians may feel more clinically competent and have higher professional self-esteem by having unfettered access to these powerful diagnostic tools, rather than referring challenging cases to specialists.

Unfortunately, distinguishing scans ordered by specialists and primary care doctors is difficult because, although Medicare claims data does provide information about place of service, it does not identify source of referral. Thus, a CT referred from the ED is billed out as performed in that same place, e.g., "physician's office" – as one referred by a physician in the community. Accordingly, we were not able to distinguish in our claims data between "orderers," "performers," "readers," and "billers." Using more sophisticated data methods, others have found that there has been a recent shift in who orders and performs advanced imaging services including CTs and MRIs, although not specific to the brain: the share of physician office-based CT and MRI scans performed by non-radiologist physicians has increased dramatically in recent years (DHHS OIG, 2007). They appear to be relying on several approaches to evading the federal restrictions on self-refer, most commonly lease (or time-sharing arrangement) or payment per scan (so-called "pay-per-click") arrangements (Mitchell, 2007).

One study found that the growth rate from 2000 to 2005 for all MRI scans was 83% for radiologists and 254% for non-radiologists (Levin, 2008). In this study, the non-radiologic specialties most actively involved in performing MRI scans were orthopedists (161,000 Medicare studies in 2005), neurologists (63,000), primary care physicians (58,000), internal medicine subspecialists (34,000), and neurosurgeons (21,000). (This study did not distinguish among the many MRI procedures, but the presence of neurologists and neurosurgeons among the specialties implies that MRI of the brain was one of the services implicated in the non-radiology self-referrals.)

Similarly, a U.S. Department of Health and Human Services (DHHS) Office of Inspector General study found that, between 1995 and 2005, the percentage of advanced imaging scans

interpreted by radiologists fell from 83% to 58% (DHHS OIG, 2007). This study also found that the share of advanced imaging services performed in Independent Diagnostic Treatment Facilities (IDTFs) increased from 2.6% to 23% between 1995 and 2005. Recent reports suggest that physicians are using lease, time-share, and pay-per-click arrangements with IDTFs to profit by referring patients to these facilities (Casalino, 2008; Mitchell, 2007).

C. Financial Factors

Payment Structure: Experts thought that the technical component of fees under the Medicare fee schedule for MRI scans in particular had been generously valued in relationship to the underlying capital costs of acquisition, amortization and depreciation. Accordingly, MRIs were seen as a highly lucrative service to offer. A recent article by MedPAC staffers detailed the reasons for apparent overvaluation of imaging services (Winter, 2008). The Centers for Medicare and Medicaid Services (CMS) uses assumptions for calculating imaging equipment costs that may be inaccurate and uses newer practice cost data for some, but not all, specialties. In addition, CMS's method of adjusting for geographic differences in input prices may overpay for imaging services in high-cost areas and underpay in low-cost areas.

According to a provision of The Deficit Reduction Act of 2005 (DRA), Medicare fees for certain imaging services covered by the physician fee schedule may not exceed what Medicare would pay for the same services under Medicare's hospital outpatient prospective payment system (OPPS), effective for calendar year 2007. The OPPS cap sparked intense reaction from the imaging provider community. Specifically, physician organizations and imaging manufacturers have suggested that reduced fees as a result of the cap may inhibit physicians' willingness to provide imaging services for Medicare beneficiaries, which in turn could affect Medicare beneficiary access to such services.

Asked to study the impact of the DRA provision, the Government Accountability Office (GAO) found that nearly all MRIs and CTs were paid at the OPPS rate. Among the three most

commonly performed MRIs subject to the cap, fee reductions ranged from about 21 to 40 percent. CPT code 70553 "MRI of the brain with and without contrast" was reduced the most of any of the commonly performed advanced imaging services, with a reduction in payment of 40.4%, suggesting that it had indeed been a highly remunerative service[‡] (GAO, 2008).

Medicare Coverage Decisions: Not a factor.

4. Summary

CT and MRI scans of the brain have continued to grow in volume much faster than the average for all services for a variety of clinical conditions. Although aging of the population and specific new clinical indications for these scans provide some of the impetus for the growth, experts think that other factors are mostly responsible, in particular the combination of ubiquity of ready availability of the advanced technologies in most communities and a growing clinical willingness to use CT and MRI scanning as a basic screening test, in some cases even substituting for the basic elements of evaluation and management services, i.e., history taking, physical examination, and clinical decision-making. Contributing to the growth is the desire by patients to have reassurance about the absence of serious underlying conditions, such as cancer, by having a non-invasive imaging test that is paid for by Medicare and supplemental insurance without questions asked, and which mostly produce no harm.[§]

During the period of 2000 to 2006, MRIs were generously reimbursed. The main beneficiaries of the payment, namely, radiology practices and independent diagnostic testing facilities, were

[‡] The GAO study found that from 2000 through 2006 both expenditures for and utilization of Medicare physician imaging services increased, but in 2007 expenditures declined while utilization continued to rise. From 2000 to 2006, on a per-beneficiary basis, expenditures increased 11.4 percent per year and in 2007 declined 12.7 percent. The implementation of the OPPS cap had the greatest impact on the decline in Medicare physician imaging expenditures in 2007, although other factors also contributed to this trend. Per-beneficiary utilization rose 5.9 percent per year from 2000 to 2006 and continued to increase in 2007, although at a slower rate of 3.2 percent.

[§] A recent NEJM review concluded that radiation dosage with CT scanning is higher than for most other imaging services that involve radiation but generally the cost/benefit ratio is acceptable if the CT scans are appropriately used. (Brenner, 2007)

not in a position to self-refer or to preferentially perform MRIs, rather than CTs, as they mostly respond to requests from referring physicians for specific imaging procedures, whether or not they agree with the referring physician's judgment. However, during this time, there was a shift toward greater ordering and performance by non-radiologists, who in some instances profit from self-referral.

Section References

(AAND) (2008) Guidelines Abstracted from the American Academy of Neurology's Dementia Guidelines for Early Detection, Diagnosis and Management of Dementia (Last accessed December 10, 2008) http://www.americangeriatrics.org/products/positionpapers/aan_dementia.shtml

ACR Appropriateness Criteria (2007) Dementia and Movement Disorders (Last accessed December 10, 2008) http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonNeurologicImaging/NeurodegenerativeDisordersUpdateinProgressDoc9.aspx

ACR Guideline (2006) Headache (Last accessed December 10, 2008) http://www.guideline.gov/summary/summary.aspx?doc_id=9599&nbr=005120&string=headache

ACR Guideline (2008) Practice Guideline for the Performance and Interpretation of MRI of the Brain (Last accessed December 10, 2008) (http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/head-neck/mri_brain.aspx)

Brenner DJ and Hall EJ. (2007) Computed Tomography – An Increasing Source of Radiation Exposure. New England Journal of Medicine; 357:2277-2284.

Casalino LP. (2008) The Synthesis Project: Physician Self-Referral and Physician-Owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No. 15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf.

(DHHS OIG) Department of Health and Human Services, Office of the Inspector General. (2007) Growth in Advanced Imaging Paid Under the Medicare Physician Fee Schedule. OEI-01-06-00260. (OIG: Washington, D.C., October, 2007).

(GAO) Government Accountability Office, (2008) Medicare: Trends in Fees, Utilization, and Expenditures for Imaging Services before and after Implementation of the Deficit Reduction Act of 2005 GAO-08-1102R September 26, 2008 http://www.gao.gov/docsearch/app_processform.php

Levin D, Rao VM, Parker L et al. (2008) Ownership or Leasing of MRI Facilities by Nonradiologist Physicians is a Rapidly Growing Trend. *Journal of the American College of Radiology*; 5: 105-109.

Mitchell, JM. (2007) The Prevalence of Physician Self-Referral Arrangements after Stark II: Evidence from Advanced Diagnostic Imaging. *Health Affairs Web Exclusive;* 26: w415-w424.

Tynan A, Berenson RA, and Christianson JB. (2008) Health Plans Target Advanced Imaging Services: Cost, Quality, and Safety Concerns Prompt Renewed Oversight. Center for Studying Health System Change, Issue Brief #118, February, 2008

Winter A and Ray N. (2008) Paying Accurately for Imaging Services in Medicare. *Health Affairs*; 27:1479-1490.

Appendix IV

CT/MRI Scans of Lumbar/Spine

1. Background On Service

A .Condition Associated with the Service

There are a range of conditions for which computed tomography (CT) and magnetic resonance imaging (MRI) with and without contrast material are performed. Examples of well accepted indications for these studies include: sciatica (leg pain in a distribution that suggests nerve impingement at or near the spinal cord) with or without associated back pain and focal neurologic deficits, major trauma, suspicion of an infectious process involving the spine or adjacent structures, suspicion of cancer, significant scoliosis, suspicion of spinal stenosis (narrowing of the spinal canal), and a range of other conditions. These imaging modalities are also used for patients with either acute or chronic low back pain. The indications for these imaging procedures for back pain without other specific findings are not settled, but back pain is a source of many of the scans that are performed.

B. Description of Services

CT and MRI are described in the previous appendix.

2. Observed Growth from 2000 to 2006

For the six current procedural terminology (CPT) codes that reflect the various CT and MRI procedures of the lumbar spine, based on varying use of contrast material, the overall growth was 96%. However, there was disproportionately high growth in two MRI codes, which are also the two codes that represent most of the spending for this family of services.

In contrast to the situation with CT and MRI of the head, more than 90% of the combined CT and MRIs of the lumbar spine are MRIs. CPT code 72148 "MRI without contrast" grew 103% between 2000 and 2006 and CPT code 72158, "MRI without contrast followed by contrast" grew 121%. This pattern presumably reflects the lower need to perform advanced imaging services of the back quickly and safely in the emergency department setting, and the fact that CT of the spine is not very good at detecting abnormalities of the discs, nerves, or spinal cord.

3. Potential Reasons for Growth

A. Clinical Factors:

Epidemiologic Trends: Over the long term, population aging and the accompanying age-related degenerative disease of the spine should increase the size of the population for which imaging of the lumbar spine is performed. Increasing obesity is another factor that contributes to degenerative spine disease.

Better Evidence of Benefit or Benefit to New Types of Patients: There seems to be agreement among experts and across various clinical practice guidelines that MRI scanning early in the course of an episode of back pain does not improve clinical outcomes or reduce costs of care (Gilbert, 2004; ACR Guideline, 2005). MRI is best used to rule out the possibility of impending neurologic injury, infection, or tumor in a clinical context when these underlying problems might be present (Carragee, 2005). Appropriate candidates for MRI include patients with low back pain who have associated neurologic symptoms or signs; associated systemic infections; risk factors for cancer, infection, or occult fractures.

There is lack of agreement on whether MRI scanning is useful in evaluating patients who have persistent pain in the absence of neurological signs or symptoms after four to eight weeks. A recent review of approach to managing patients with persistent low back recommended an MRI scan in this situation (Carragee, 2005), and our experts thought that advanced cross-sectional

imaging as provided by an MRI was becoming an ordinary and expected part of the low back pain evaluation, especially in the elderly population with osteoporosis who are at risk for vertebral fractures as well as complications of degenerative joint disease.

However, a joint clinical practice guideline recently promulgated by the American College of Physicians and the American Pain Society (ACP and APS, 2007), concluded that the evidence showed that routine advanced imaging in patients with nonspecific low back pain is not associated with improved patient outcomes and identifies many radiological abnormalities that are poorly correlated with symptoms (Jarvik, 2002), but could lead to additional, possibly unnecessary interventions. (Jarvik, 2003; Lurie, 2003).

As discussed in more detail in the appendix on spinal injection procedures for low back pain, there is disagreement among experts about whether specific findings on MRI scans of the low back permit better targeting of injection interventions, such as abnormal spinal facets that might benefit from anesthetic injections or neuroablation procedures.

As noted above, most advanced imaging procedures of the low back are MRIs rather than CTs. This preference results from the broadly perceived added benefit of resolution of soft tissue findings such as the disc and spinal cord. One of our experts thought that for many of the indications, this added benefit is not necessary, yet involves a more time-consuming and expensive procedure.

New Technology: Not applicable.

Diffusion:

Patient Demand: As noted for CT and MRI of the brain, patients have become increasingly aware of advanced imaging modalities. Further, they are less likely than previously to “live

with" chronic pain and so are more likely to obtain care from physicians who see MRI as a standard part of the diagnostic workup for patients with persisting back pain.

Provider Uptake: Experts thought that ready performance of advanced imaging for low back problems increased the level of comfort and confidence for the referring physicians and in some situations had become routine, even substituting for a complete history and physician, but at a higher cost and without clinical payoff in most situations. One likened the routine use of MRI technology for uncomplicated low back pain as "killing the fly with a sledgehammer" but explained the impulse of ordering physicians to not miss a treatable diagnosis, even if rare.

As discussed more fully in the section on CT/MRI of the brain, CT and MRI scanners have become readily available in most communities; during the 2000-2006 period, MRIs in particular were viewed as a profitable service under Medicare and private insurance, further enhancing their continued broad diffusion throughout most communities' health delivery systems.

C. Financial Factors

Payment Structure: When the practice owns its own advanced imaging equipment or is able to lease equipment on a "per click" basis, the ordering physician can benefit financially from performing services for what are perceived as generous payments for MRI scans. Experts thought that during the period of 2000 to 2006 practices with sufficient size and scope, such as spine centers organized by orthopedists and/or pain specialists, purchased or leased MRIs in order to enhance practice revenues (Berenson, 2006). Similar to the situation for MRI of the brain, the Government Accountability Office (GAO) reported that MRI of the lumbar spine without contrast was subject to a reduction under the Deficit Reduction Act of 2005 (DRA) provisions limiting payment of physician-provided imaging services to no more than that provided under the hospital outpatient prospective payment system (OPPS). The value of this service was reduced 24.6%, from a national rate of $557.09 to $419.90 (GAO, 2008). Presumably, related advanced imaging services were reduced as well.

Readers are referred to the discussion in the write-up of CT/MRI of the brain for more detail on the self-referral issue and induced demand issue.

Medicare Coverage Decisions: Not applicable.

4. Summary

CTs and MRIs of the lumbar spine have experienced great growth – overall, nearly doubling in between 2000 and 2006, with most of the growth from MRIs, which have been preferred because they provide greater visualization of soft tissues and because these imaging services are not typically performed on an emergency basis with unstable patients. The widespread and increasing availability of scanners and the desire by patients and physicians to have greater assurance that there has not been significant missed pathology have combined to support the volume growth. Experts agree that practicing physicians responsible for referring for most of these scans did not personally benefit from the generous reimbursements for the MRIs during the study period. However, the situation began to change shortly before 2006, with greater physician ownership and lease arrangements of MRI equipment.

Section References

ACP and APS (2007) Diagnosis and Treatment of low back pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. (Last accessed December10, 2008) http://www.guideline.gov/summary/summary.aspx?doc_id=11515&nbr=005968&string=low+AND+back+AND+pain

ACR Guideline (2005) Low Back Pain (2005) (Last accessed December 10, 2008) http://www.guideline.gov/summary/summary.aspx?doc_id=8599&nbr=004786&string=low+AND+back+AND+pain

Berenson RA, Bodenheimer T, Pham HH, (2006) Specialty-Service Lines: Salvos in the New Medical Arms Race *Health Affairs*, Web Exclusive; 25(5): w337-w343

Carragee EJ. (2005) Persistent Low Back Pain. *New England Journal of Medicine*; 353; 18:1891-1898

(GAO) Government Accountability Office, (2008) Medicare: Trends in Fees, Utilization, and Expenditures for Imaging Services before and after Implementation of the Deficit Reduction Act of 2005 GAO-08-1102R September 26, 2008 http://www.gao.gov/docsearch/app_processform.php

Gilbert F, Grant A, Gillan M, et al. (2004) Scottish Back Pain Group. Low Back Pain: Influence of Early MR Imaging or CT on Treatment and Outcome – Multicenter Randomized Trial. *Radiology*; 231:343-351.

Jarvik JG and Deyo RA. (2002) Diagnostic Evaluation of Low Back Pain with Emphasis on Imaging. *Annals of Internal Medicine*; 137:586-597.

Jarvik JG, Hollingsworth W, Martin B et al. (2003) Rapid Magnetic Resonance Imaging verses Radiographs for Patients with Low Back Pain: A Randomized Controlled Trial. *Journal of the American Medical Association*; 289:2810-2818.

Lurie JD, Birkmeyer NJ, Weinstein JN. (2003) Rates of Advanced Spinal Imaging and Spinal Surgery. *Spine*; 28:2028-2037.

Appendix V

Diagnosis and Medication Therapy for Macular Degeneration

1. Background On Service

A .Condition Associated with the Service

Age-related macular degeneration (AMD) is a disease associated with aging that gradually destroys sharp, central vision. Central vision is needed for common daily tasks such as reading and driving. AMD affects the macula, the part of the eye that allows you to see fine detail. AMD causes no pain. AMD is typically characterized as either non neo-vascular ("dry," atrophic or non-exudative) or neovascular ("wet" or exudative or advanced). The clinical differentiation is relatively straight forward, in the hands of retina specialists, which are the dominant subspecialty that addresses problems of AMD. Neovascular AMD is characterized by new blood vessel growth in the choroid (the vascular layer of the eye between the retina and sclera) and its sequelae, resulting in reduced and distorted light sensation in these areas of the retina.

AMD is the leading cause of irreversible blindness in people 50 years of age or older in the developed world. More than 8 million Americans have AMD, and the overall prevalence is projected to increase by more than 50% by 2020 (Friedman, 2004). The wet, neovascular form of the disease affects about 1.75 million. Risk factors include advancing age, genetic factors, smoking history, white race, obesity, high dietary intake of vegetable fat and low intake of antioxidants and zinc. Aging is the dominant risk factor with prevalence increasing from 0.1% among those 43-54 to 7.1% among people 75 years or older (Klein, 1992). Once macular degeneration develops in one eye, there is substantial probability – 43% in one report – (Age-Related Disease Study Research Group, 1997) of its development in the other eye within 5 years.

B. Description of Services

Diagnostic Tests: Specific ophthalmic imaging techniques, especially intraveneous fluorescein angiography, augment clinical examination. An alternative test, optical coherence tomography (OCT), is noninvasive and can help elucidate retinal abnormalities by creating a cross-sectional image of the retina with the use of reflecting light rays. For both diagnosis and ongoing disease surveillance, OCT has the potential to replace angiography as the preferred test. Angiography is a more elaborate test, takes longer, requires physician administration, and has potential side effects. For now, the standard of care seems to be angiography for diagnosis and OCT for ongoing disease surveillance although there remains substantial variation among retina specialists.

Treatment: Photodynamic therapy (PDT) with verteporfin, which became available in the late 1990s, was introduced and approved for payment in Medicare under two National Coverage Decisions that provided specific indications for its use in a subclass of wet AMD. Its benefit in reducing disease progression was marginal at best.

A new class of anti-angiogenic drugs – monoclonal antibody antagonists to vascular endothelial growth factor (anti-VEGF) – has changed the treatment of neovascular AMD and is the reason for recent dramatic rises in both diagnostic studies and drug injections for AMD. This class of drugs not only arrests progression but also is associated with some improvement in retinal examination findings as well as some visual improvement. Injection directly into the vitreous part of the eye, performed in the office setting, avoids systematic administration and possibly reduces the incidence of potential systemic adverse side effects. In trials, the anti-VEGF agents were injected monthly. Given the cost of the drug and remaining uncertainty about the correct dosing schedule, interviewed experts thought that most retina specialists were administering their preferred drug somewhat less often, perhaps every two months or so.

2. Observed Growth from 2000 to 2006

The generic code for eye injections (CPT 92135) was rarely used until the new treatments for AMD were developed. Accordingly, allowed charges per beneficiary grew from $0.02 in 2000 to $3.14 in 2006 (15,355.2%). The diagnostic tests – fluorescein angiography and OCT also showed significant increases. The charges per beneficiary for the former (CPT 92235) increased from $3.43 to $5.77 (66.1%) and for the latter from $1.03 to $6.17 (499.3%).

3. Potential Reasons for Growth

A. Clinical Factors:

Epidemiologic Trends: Although there is a general trend toward aging and obesity within the Medicare population, these influences would only be a minor factor explaining volume growth between 2000 and 2006.

Better Evidence of Benefit or Benefit to New Types of Patients: Not applicable.

New Technology: Pegaptanib (Macugen) was the first anti-VEGF agent approved for AMD by the Food and Drug Administration (FDA), in December, 2004. A major therapeutic breakthrough occurred in 2006, when a phase 3 trial showed substantial and, compared to pegaptanibpegaptanib, superior, benefits from another anti-VEGF agent, ranibizumab (Lucentis). FDA approved ranibizumab for treatment of neovascular AMD in June, 2006.

Bevacizumab (Avastin), a molecule which shares the same active portion as ranibizumab, is increasingly being used off-label in place of ranibizumab, partly because of its much lower cost. The price of an intravitreal dose of ranibizumab is $1950 and of bevacizumab about $30 (Jager, 2008). In fact, reports of benefit from intravitreal use of bevacizumab actually preceded the more definitive findings for ranibizumab and there was apparently word of mouth adoption by 2004. Furthermore, ranibizumab was not released until 2006, so many retina specialists began using bevacizumab before FDA approved either pegaptanib or ranibizumab and became accustomed to

it. Many continued to use bevacizumab, even when the likely equivalent drug – ranibizumab – became available in 2006, partly because of familiarity and partly because of its lower cost.

Data from definitive long-term studies comparing ranibizumab and bevacizumab in AMD are expected in about 2 years. However, several short-term studies of intravitreal bevacizumab have shown improvement in visual acuity that is similar to that of ranibizumab with comparable side effects. This produces a dilemma for retina physicians because the expensive ranibizumab has an on-label indication whereas bevacizumab use in AMD is off-label. The American Academy of Ophthalmology outlined a "Preferred Practice Pattern" for AMD in 2006, supporting the approved ranibizumab injection for neovascular AMD and also bevacizumab as an off-label use, based on the existing comparative studies (AAO).

Currently, studies have not determined how long treatment needs to be continued or how long benefits are sustained. The longest trials have continued only two years. Although the disease seems to burn out in some cases, it may be that treatment should be continued for the duration of patients' lives.

Experts agree that new availability of drugs that slow the progression of AMD has been the dominant reason for explosion in the growth of services and that there is little reason to think there is inappropriate use. Although there is a much larger pool of patients with dry macular degeneration than the wet form that responds to treatment, there was agreement that retina specialists should have little difficulty distinguishing among the different forms, so there is probably little inappropriate use on patients who would not benefit.

Diffusion:

Patient Demand: Patients may be aware that they are experiencing vision loss, but the diagnosis of AMD currently depends upon clinical suspicion by a general ophthalmologist and then diagnosis and treatment recommendations by a retina specialist. Although there have been some

direct-to-consumer marketing approaches about the need for annual eye examinations among the elderly, during the period 2000-2006 there was no concerted direct-to-consumer advertising about treatment for AMD with the anti-VEGF drugs *per se*.

Some patients are unaware of early, subtle changes in vision, so that periodic examinations by skilled clinicians are necessary because early identification and treatment now can lead to better visual outcomes as discussed below. One of our experts agreed that there may be significant under-diagnosis because of patients' ascribing visual disturbances to other causes, such as cataracts, and lack of routine eye exams even in seniors. There do not seem to be good estimates of the prevalence of undiagnosed AMD, and our experts did not think that greater awareness of the disease by patients or referring physicians would explain the dramatic increase in treatment in recent years.

The clinical trials on which ranibizumab's FDA approval was based relied on monthly injections – less frequent injections, e.g, quarterly, eliminated the improvement in visual acuity that was observed with monthly injections. The very high price of ranibizumab and the requirement for frequent administration – perhaps as often as monthly – created a practical cost problem because of the high price of ranibizumab.

The cost sharing associated with ranibizumab could be an important factor in affecting demand for that particular drug therapy.

Provider Uptake: For these services, there is reason to believe that the relatively small number of retina specialists – about 2000 nationwide – was closely following clinical trials and the clinical peer reviewed literature very closely and quickly adopted new interventions even before they were formally approved by FDA and recognized for payment by the Centers for Medicare and Medicaid Services (CMS). From the Relative Value Update Committee (RUC) database, 99.75% of claims for code 67221 are submitted by ophthalmologists. (No information was available about distribution between general ophthalmologists and retina specialists, but the

experts agreed that given the specialized expertise and equipment needed for diagnosis, it would be unlikely that physicians other than retina specialists would be submitting claims.) During this period, there did not appear to be significant marketing to retina specialists by Genentech, the manufacturer of both ranibizumab and bevacizumab. Indeed, Genentech has come under scrutiny for its purported attempt to limit the availability of the ophthalmic form of bevacizumab to try to direct purchase of the much more expensive ranibizumab. (Senator Kohl, 2007).

C. Financial Factors

Payment Structure: There did not appear to be issues in the pricing of the services physicians are billing for other than those related to the cost of ranibizumab, as already discussed.

Medicare Coverage Decisions: No relevant issues with regard to the use of the anti-VEGF agents. There were controversial national coverage decisions regarding approval of use of PDT, but the controversy has subsided with the replacement of PDT by the more effective modality.

4. Summary

The adoption and use of new treatments for macular degeneration seems to be an example of increased volume mostly because of a new treatment with clinical benefits for a common and serious condition. In this case, fairly rapid uptake followed directly from the clinical literature, supported by FDA approval. However, given the common off-label use of bevacizumab for wet AMD, which has been endorsed in practice guidelines, it appears that the clinical breakthroughs and rapid dissemination throughout the retina specialist community was the driving factor.

An important issue that may be resolved if the head-to-head comparisons of ranibizumab and bevacizumab prove equivalence, relates to decisions on whether to use bevacizumab or ranibizumab, one expensive and approved, the other inexpensive and off-label, with presumably similar clinical effects. Of note, although the focus here has been the diagnostic modalities for

identifying and following AMD and on the relatively straightforward injection procedure that has demonstrated explosive growth, the cost of the drugs, especially ranibizumab, which are covered by Medicare as Part B drugs, are included in the calculation of the sustainable growth rate (SGR) target.

Section References

(AAO) American Academy of Ophthalmology: Preferred Practice Pattern. Age-Related Macular Degeneration, Available at http://one.aao.org/CE/PracticeGuidelines/PPP_Content.aspx?cid=0e2b5946-d493-4a4a-80fa-6f40841b1405 (Last accessed December 10, 2008)

Age-Related Eye Disease Study Research Group. (1997) A Randomized, Placebo-Controlled, Clinical Trial of High Dose Supplementation with Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss: AREDS report no 8. *Archives of Ophthalmology*; 115:741-7.

Freidman DS, O'Colmain BJ, Munoz B. et al. (2004) Prevalence of Age-Related Macular Degeneration in the United States. *Archives of Ophthalmology*: 122:564-72.

Jager RD, Meiler WF, Miller JW. (2008) Age-Related Macular Degeneration. *New England Journal of Medicine*; 358:2606-17.

Klein R, Klein BE, Linton KL. (1992) Prevalence of Age-Related Maculopathy: the Beaver Dam Eye Study. *Archives of Ophthalmology*; 99:933-43.

Senator Kohl, Herb (2007) U.S. Senate: Special Committee on Aging November 2007 letter to Dr. Desmond-Hellmond, Genetech, Inc. (Last accessed December 10, 2008) http://aging.senate.gov/letters/genentechltr.pdf

Appendix VI

Electrodiagnostic Testing for Nerve Problems

1. Background on Service:

A. Condition(s) Associated with the Service:

The main indications for performing motor and sensory nerve conduction studies are carpal tunnel syndrome (CTS), peripheral neuropathy (associated with diabetes, longstanding heavy alcohol use, Vitamin B12 deficiency and many other conditions common among the elderly), and cervical and lumbar radiculopathy (pain, weakness, or numbness of a nerve root coming out of the spine). Less common indications would include other types of nerve entrapment (e.g. ulnar neuropathy due to compression at the elbow), lumbar spinal stenosis with nerve involvement, and limb and torso pain where there is a question of cervical, thoracic, or lumbar radiculopathy (Chemali, 2005).

B. Description of Services

Electrodiagnostic testing helps in diagnosing and developing treatment plans for patients with diseases of the peripheral nervous system and muscles. It may include both a needle electrode examination (electromyography) and nerve conduction studies. Nerve conduction studies (NCSs) are performed to assess the integrity and diagnose disease of the peripheral nervous system; specifically, they assess the speed, size, and shape of the nerve response to electrical stimulation. Typically, nerve conduction studies are performed by the physician alone or by a trained technician working under supervision. Motor, sensory, and mixed NCSs and late responses (F-wave and H-reflex studies) may be complementary and performed during the same evaluation.

Needle electromyography (EMG) refers to the recording and study of the electrical activity of muscle using a needle electrode and it always requires a physician to perform the test in a

dedicated facility According to the Relative Value Update Committee (RUC) database, a single NCS has an intra-service time of 5 minutes, compared to 34 minutes for current procedural terminology (CPT) code 95860 – needle electromyography of one extremity.

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

The various codes for motor and sensory nerve conduction studies have grown very fast and at a much faster rate than growth in EMGs. For example, per capita per beneficiary allowed charges for sensory nerve conduction tests (CPT 95904) have increased from $1.47 to 5.39 (265.5%) and those for motor nerve conduction, with F-wave study, increased from $1.01 to $4.67 (361.7%). In contrast, per capita charges for a one extremity needle EMG (CPT 95860) has increased from 0.45 to 0.65 (net of the conversion factor increase), or 44%.

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: The growth in diabetes and the association of carpel tunnel syndrome with obesity, which is becoming much more common, may lead to increase in conditions for which these tests are performed. They do not, however, explain the substantial increases observed in the six year period of this study.

Better Evidence of Benefit or Benefit to New Types of Patients: Our experts agree that the indications for these studies have not changed in recent years, the testing approach has long been standardized, and there have been no important epidemiological changes in the Medicare population. As discussed below, the American Association of Neuromuscular & Electrodiagnostic Medicine does not consider the newer portable device administered under the supervision of a generalist physicians to be an acceptable alternative to traditional nerve conduction studies, which, they maintain, should usually be accompanied by a needle EMG.

Further, experts agree that many of the conditions for which electrodiagnostic testing is being performed can be evaluated clinically without need for confirmatory findings from these tests and that the indications for many of the studies being performed is marginal at best.

New Technology: Increasingly nerve conduction studies are being done in any physician office setting, facilitated by an actively marketed, Food and Drug Administration (FDA)-approved portable nerve conduction apparatus. A widely used handheld device, manufactured by NeuroMetrix has been on the market since May 1999. (Neurometrix, 2008) A more recently approved portable testing device is produced by Brevio. These new testing systems do not involve needles so are better tolerated by patients and can be performed by a non-physician. Indeed, a recent patient testimonial on the manufacturers' web site (NeuroMetrix, 2007) raved, "It didn't hurt, and it was over in a few seconds." From the Center for Medicare and Medicaid Services (CMS) data, it is not possible to tell how many of the claims used established nerve conduction study technology and how many used the new portable devices.

B. Diffusion:

Patient Demand: Patients rarely ask for these studies because their existence is not widely known to the public. Further, a needle EMG can be painful. However, the experts do think there has been an increase in patients' seeking relief for conditions, such as cervical arthritis and low back pain, that in the past they might have tolerated. They are then more often referred to facilities that order the electrodiagnostic testing as a prelude to other treatments, such as surgery or other therapeutic interventions, such as back injections.

Provider Uptake: Until recently, NCSs and EMGs were performed in a dedicated laboratory run by a physician with special training in this testing (AANEM, 2006). Typically such labs are run either by neurologists or physical medicine and rehabilitation physicians, who are able to take specialized board examinations specific to electrodiagnostic medicine. Recently, however, portable devices have been developed to allow these NCSs, but not EMGs, to be performed in

the generalist physician office without specialized training. Automated nerve conduction devices use computerized software to deliver, measure, and analyze the response and provide a detailed report, which the ordering physician can review and sign off on in order to receive reimbursement for interpretation in addition to the technical charge for conducting the test itself. The experts think the availability of this easy to use, hand held device to record nerve conduction might explain the explosive growth in the nerve conduction studies, especially compared to the modest growth in EMGs. Experts also point to the development of pain and spine clinics as a source of major increase in growth of studies outside of qualified labs.

The availability of the easy-to-use and easy-to-bill-for portable device studies has raised two issues regarding appropriateness. The first is whether the portable device provides acceptable diagnostic utility comparable to that provided by conventional studies. The specialty societies representing the experts do not think the effectiveness of the portable tests have been proven (AANEM, 2006). The second is whether NSCs should be routinely performed without complementary performance of an EMG at the same time. In 2006 the American Association of Neuromuscular and Electrodiagnostic Medicine (AAMEM) issued a position statement that illustrates how standardized NCSs performed independent of needle EMG may miss data essential for an accurate diagnosis. It concluded that "… except in unique situations, NCSs and needle EMG should be performed together in a study design determined by a trained neuromuscular physician" (AANEM, 2006). These recommendations, whether or not they are correct, are not being followed in Medicare policy (see next section). However, these specialty societies have a vested interest in perpetuating the use of the more comprehensive tests by their members.

The Aetna coverage policy on the NeuroMetrix device branded as NC-Stat cites a recently performed technology assessment performed by the Washington State Department of Labor and Industries (Morse, 2006):

> "The evidence evaluating the use of NC-stat is most abundant for nerve testing that may be useful to diagnose or screen for conditions at the wrist (i.e., median and ulnar nerve studies). There is very little or no available evidence (high quality, peer-reviewed) supporting the use of NC-stat and specific biosensors for testing of nerves in the lower extremities. . . . At this time there is not adequate scientific evidence to conclude that NC-stat is equivalent to traditional nerve conduction study methods for use in evaluating the functioning of the median, ulnar, peroneal, sural or tibial nerves. The diagnostic accuracy of NC-stat is not yet demonstrated in the scientific literature to be equivalent to traditional or gold-standard testing methods. NC-stat is therefore considered experimental and investigational. … NC-stat is considered controversial as the performance of testing at the point-of-service may not be supported by recommendations of the American Association of Neuromuscular & Electrodiagnostic Medicine.

Consistent with the availability and sales of new portable equipment to perform NCSs, a broader range of physicians are submitting claims for these studies. For example, in 2006, there were more then 4 million claims submitted for CPT 95905 – sensory nerve conduction study. About 20% of the claims were submitted by primary care physicians in family practice, general practice, or internal medicine. As already discussed, the experts were concerned about the diagnostic accuracy of these newer machines and the lack of expert physicians' supervision. One expert thought that the lack of a corresponding increase in use of EMG was almost "smoking gun" evidence of misuse of NCSs; the fact that EMGs are not increasing with NCS increases suggests inappropriate performance of stand-alone NCSs.

C. Financial Factors:

Payment Structure: All three experts agreed that, in the words of one of them, "electrodiagnostic testing is very remunerative for those who provide the service. It is possible that providers are referring more patients for electrodiagnostic testing to themselves or their colleagues in order to make up for lost revenue in other areas." Further, "reimbursement for

electrodiagnostic testing is much greater than for cognitive services. This prompts more referrals for testing and more intense testing when the patient is seen in the electrodiagnostic laboratory." On the perceived overuse of the H-reflex and motor nerve test with rarely needed F-wave study, "A lot of this is cookbook. Lots of times, the test is done by a technician, who is told by the physician to do everything to everyone."

Medicare Coverage Decisions: Medicare has not made National Coverage Decisions about these studies which are relatively "low tech," in broad use, and performed for a myriad of conditions. Clinical controversy relates to the reliability of the results of nerve conduction studies conducted with use of the new hand held devices. The manufacturer of the most widely used portable device stated in a recent company statement that insurers still regard the device as experimental and investigational, which is causing physicians using the device "to experience higher levels of claims denials, longer periods of time to receive reimbursement, and an overall environment of uncertainty" (Neurometrix2, 2007).

That view is independently confirmed by a review of health insurers' position statements. For example, Blue Cross and Blue Shield of Alabama's specifically exclude coverage for "NCS … portable hand-held devices, since these devices are incapable of wave form analysis. Examples of portable hand-held noninvasive nerve conduction testing devices include, but are not limited to, NC-Stat System, and the Brevio® nerve conduction monitoring system" (Blue Cross and Blue Shield of Alabama, 2008). Aetna, CIGNA and a number of other insurers have similar statements in their coverage policies (Aetna, 2008; CIGNA, 2008). Private insurers also frequently put limits on the number of nerve conduction tests that can be submitted at the same time.

Reimbursement from Medicare based on CPT coding, without consideration of the testing device used, appears straightforward.

4. Summary

There has been a dramatic increase in nerve conduction studies without good clinical or epidemiological explanation. Our experts think that financial incentives are driving the increase in motor and sensory nerve conduction studies, facilitated by new portable equipment that makes performance in the office very easy. The magnitude of use of the new portable device for these tests in Medicare is not known. The disconnect between the modest increase in EMGs on the one hand and large increase in nerve conduction studies on the other may be evidence of inappropriate testing for financial gain.

The RUC data documents that some of the increase in use results from use, probably inappropriate, by primary care physicians, but this cannot represent more than about a third of the increase. Experts conjecture that pain and back clinics – the "usual suspects" in the words of one expert – are also responsible also for much of the inappropriate increase.

Section References

Aetna (2008) Clinical Policy Bulletin: Nerve Condition Velocity Studies no. 0502 (Last accessed December 10, 2008) http://www.aetna.com/cpb/medical/data/500_599/0502.html

American Association of Neuromuscular & Electrodiagnostic Medicine. (2006) Position Statement, Proper Performance and Interpretation of Electrodiagnostic Studies 2006 Muscle Nerve 33**:** 436–439, 2006. Available at http://www.aanem.org/documents/ProperPerformance.pdf.

Blue Cross and Blue Shield of Alabama Coverage Criteria (2008): Neuromuscular and Electrodiagnostic Testing: (Last accessed December 10, 2008) https://www.bcbsal.org/providers/policies/final/228.pdf

Chemali K and Tsao B. (2005) Electrodiagnostic Testing of Nerves and Muscles: When, Why and How to Order. *Cleveland Clinic Journal of Medicine*; 72:37-48.

CIGNA HealthCare Coverage Position: Nerve Conduction Velocity Studies Including Late Response (H-reflex and F wave) available at (July 2004) (revised July 2008) (Last accessed December 10, 2008)

http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0117_coveragepositioncriteria_nerve_conduction_velocity_studies.pdf.

Morse J. (2006) NC-stat® System, NeuroMetrix® Inc. (Nerve Conduction Testing System). Technology Assessment. Olympia, WA: Office of the Medical Director, Washington State Department of Labor and Industries; June 8, 2006. Available at: http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/SpecCovDec/NCstat.asp.

NeuroMetrix (2007) Dickson Doctor offers Non-Invasive Nerve Test, PDF of the *Dickson Herald* available at: http://www.neurometrix.com/Collateral/Documents/English-US/The%20Dickson%20Herald%20070926.pdf (Last accessed December 10, 2008)

NeuroMetrix (2008) Markets (Last accessed December 10, 2008 http://www.neurometrix.com/about-us-markets.htm

Neurometrix2 (2007) In Office CTS Test Still Fighting for Acceptance, PDF of *Workplace Economic*s available at: http://www.neurometrix.com/Collateral/Documents/English-US/Workplace%20Ergonomics%20News%200711.pdf (Last accessed December 10, 2008.

Appendix VII

Mohs Surgery for Skin Cancer

1. Background on Service:

A. Condition(s) Associated with the Service:

Skin cancers are thought to be the most common type of malignancy in the United States, with more than 1.3 million new cases per year as of 2001 (Alam, 2001). Of the three major skin cancers, melanoma is the most lethal but least common (58,000 new cases per year) (Essner, 2003). Mohs surgery is primarily performed for the two non-melanomatous skin cancers, basal cell carcinoma (BCC, 80% of cases) and squamous cell cancer (SCC, 20%)(Alam, 2001). Risk factors for the non-melanomatous skin cancers include age, ultraviolet light exposure, fair skin, and immunosuppression, among others (Alam, 2001; Han, 2006; Ceilley, 2006; Thissen, 1999). Both SCC and BCC are most common on the face and neck, but lesions on the trunk are not uncommon (Alam, 2001; Ceilley, 2006).

In general, patients with BCC and SCC have excellent prognoses. BCC tends to be a slow growing tumor that rarely metastasizes. However, it can invade local tissue with finger-like extensions and, if untreated or particularly aggressive, it can cause extensive damage (Bath-Hextall, 2007). About 10% of cases involve extensive local damage, recurrence, or metastasis (Thissen, 1999). SCC is more aggressive than BCC, with 5% of patients experiencing metastases and 8% experiencing recurrences by five years after diagnosis. SCC lesions on the lip and ear metastasize and recur at a much higher rate. For those with metastases, the subsequent five-year survival is only 10 to 20% (Alam, 2001).

Treatment options for both SCC and BCC include surgery, electrodessication, curettage, cryosurgery, and radiation therapy, among others. In addition, photodynamic therapy and medications can be used for BCC (Alam, 2001; Ceilley, 2006; Bath-Hextall, 2007; Minton,

2008). Although some of these therapies may be effective for selected patients, existing data indicate that surgery is the most effective treatment for BCC and SCC, particularly for high-risk tumors (Bath-Hextall, 2007; Thissen, 1999; NCCN, 2008).

B. Description of Service:

Surgical approaches include Mohs surgery and excision (Bath-Hextall, 2007; Thissen, 1999). In Mohs surgery, the tumor is resected in one to five or more stages until the surgical margin[**] is confirmed to be completely clear of tumor. At each stage, a saucer-shaped piece of tissue is removed (i.e., the bottom margin of the specimen is beveled). It is then mapped against the surgical site, prepared and flattened, and 100% of the bottom margin is examined under a microscope. If any tissue remains, the surgeon uses the map to determine which portion(s) of the surgical site require an additional stage of resection (Minton, 2008; Pennington, 2005 ; Snow, 2001). The procedures can be performed in a single day over several hours (Snow, 2001; Alam, 2001). Formally trained Mohs surgeons perform the surgical resections, examine the specimens microscopically, and perform the reconstruction. To become formally trained, physicians must complete a three-year Dermatology residency followed by a one to two-year Mohs fellowship (American College of Mohs Surgery).

In contrast, standard surgical excision produces a specimen with vertical sides and only a small slice from the center of the specimen is examined microscopically (Minton, 2008; An, 2001). A variety of surgical specialties are routinely training in performing wide excision.

Historically, the literature comparing Mohs and wide excision has generally found Mohs to be more effective. For BCC, the five-year recurrence rate has been reported to be 0.6 to 1.7% for Mohs vs. 8.1 to 10.1% for surgical excision (Rowe,1989; Thissen, 1999). For SCC, the five-year recurrence rate is about 3.1% (Alam, 2001; Rowe, 1992). However, this literature was

[**] A surgical "margin" is the boundary between the specimen that is removed and the tissue that is left in place. If examination reveals that tumor extends to the margin of the specimen, then it is likely that some tumor is left within the patient's tissue.

comprised of case series, a rather weak study design (Thissen, 1999). A 2004 rigorous randomized controlled trial comparing Mohs and wide excision for BCC found no significant difference in recurrence rates at 30 months (2% for Mohs and 3% for surgical excision) (Smeets, 2004). However, this study may have been too short to detect a difference (ref: Rowe 1989). Further, 18% of the patients who underwent surgical excision required one or more repeat procedures due to achieve negative margins (Smeets, 2004).

Commonly cited indications for Mohs include larger tumors; aggressive histologic types; tumors in certain locations; tumors in abnormal skin (such as scars) or with indistinct boundaries, or tumors with positive margins on surgical excision, recurrent tumors, and tumors in immunocompromised patients, among others (Minton, 2008; NCCN 2008).

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

Charges per beneficiary for Mohs procedures as a group (CPT 17304 through 17307[††]) grew from $3.96 to %10.41 (163%) between 2000 and 2006. In contrast, charges for surgical excision (CPTs 11642 and 11602) grew from $1.00 to $1.26 (26%).

3. Potential Reasons for Growth:

Epidemiologic Trends: Several factors appear likely to increase the incidence of BCC and SCC in the United States over the long term, including the aging of the population, increasing sun exposure and tanning, and increasing use of immunosuppressive medications to treat cancer, organ transplant recipients, and rheumatologic diseases. Although some sources report that incidence has been increasing in recent decades (Alam, 2001; Ceilley, 2006), we did not identify any recent data on the actual incidence of non-melanomatous skin cancer. Current cancer surveillance programs monitor melanoma but not BCC and SCC. Given melanoma is also associated with exposure to ultraviolet (UV) light, changes in the incidence of melanoma could,

[††] As of 2007, the CPT codes for Mohs are 17311-17315.

arguably, be used as a rough surrogate for likely changes in the incidence in BCC and SCC (Qureshi, 2008). Age-adjusted melanoma rates in the population age 65 and above increased 5.6% per year between 2003 and 2005 (SEER, 2008).

Better Evidence of Benefit or Benefit to New Types of Patients: Mohs has been well established for decades and there appear to be no new guidelines or major randomized controlled trials showing better evidence of benefit than previously believed, or showing benefits to new types of patients (Miller, 1994; Bath-Hextall, 2007; NCCN, 2008). We identified only one U.S. guideline since 1995 that addresses Mohs for BCC or SCC. A National Comprehensive Cancer Network guideline currently includes Mohs as one of several treatment first-line options for high-risk BCC or SCC, and as a second-line option for low-risk BCC or SCC if margins are positive after surgical excision (NCCN, 2008).

Some of the growth in Mohs could be for clinical situations in which it is inappropriate, unnecessary, or for which evidence is still emerging. For example, Mohs is less appropriate for lesions on the trunk and legs than for lesions on the face (NCCN, 2008). Further, Mohs is now sometimes being used for other types of skin cancers, where it is less proven; for example, melanoma, Merkel cell carcinoma, dermatofibrosarcoma protuberans, extramammary Paget's disease, and microcystic adnexal carcinoma (Pennington, 2005; Minton, 2008). We examined utilization patterns between 2000 and 2006, however, and determined that the vast majority of Mohs surgery is being performed for BCC or SCC, and that it is rarely performed on the trunk or legs.

New Technology: Not applicable.

B. Diffusion:

Patient Demand: Demand for Mohs procedures may have increased in recent years. One study found that, between 1996 and 2004, there was a shift in referral patterns at one academic center toward smaller, primary BCC tumors and away from larger, recurrent ones. This study did not

determine whether patients or primary care providers are initiating these referrals (Kaplan, 2008).

Provider Uptake: The number of providers performing Mohs surgery appears likely to have increased due to greater numbers of formally trained Mohs surgeons as well as providers with alternative or abbreviated training experiences (Snow, 2001; ASMS2, 2008). Over the past 15 years, the number of trainees completing Mohs fellowships has increased from 55 to 75 fellows per year. Interviewees reported that some surgeons with relevant expertise (e.g., plastic surgeons and dermatologists) use the Mohs sequential resection technique but have pathologists examine the specimens. Such procedures may not be billed using the standard Mohs current procedural terminology (CPT) codes so the estimates above may actually underestimate growth.

Lastly, referral patterns would also be important for future research to explore because the type of specialist patients see first is likely to determine the care that they receive. For example, if patients see a general or plastic surgeon first, they may be more likely to undergo excision because those providers are better trained in that procedure. On the other hand, if patients see dermatologists first, they may be more likely to undergo Mohs.

C. Financial Factors:

Payment Structure: There is some evidence that reimbursement for Mohs was generous during the 2000 to 2006 period and it is possible that this contributed to growth. First, some but not all interviewees perceived reimbursement for Mohs to be generous. Second, in January 2008, Medicare changed the reimbursement policies for Mohs surgery, subjecting them to a multiple procedure payment reduction. When the first stage of Mohs surgery and reconstruction are done on the same day, the lower valued of the two is reimbursed at 50% of its contracted value (ASMS, 2008). This reduction indicates that some parties believed Mohs surgery was overvalued before the reduction.

Medicare Coverage Decisions: There appear to have been no extensions or retractions of Medicare coverage for Mohs or surgical excision.

4. Summary:

There are several reasons for the recent growth in Mohs surgery: the likely increasing rates of non-melanomatous skin cancers, an expanding population of Mohs surgeons, and possibly increasing referrals to Mohs surgeons rather than the variety of surgeons who perform excision. Inappropriate or unnecessary use does not seem likely on a large scale. A recent change in reimbursement policies may attenuate the future growth in Mohs.

Section References:

Alam M, Ratner D. (2001) Cutaneous Squamous-Cell Carcinoma. *New England Journal of Medicine*; 344(13):975-83.

American College of Mohs Surgery: Overview (Last accessed December 10, 2008) http://www.mohscollege.org/about/overview.php

An KP, Ratner D. (2001) Surgical Management of Cutaneous Malignancies. *Clinics in Dermatology*; 19(3):305-20.

ASMS (2008) Letter to Members. Medicare Reimbursement Change. (Last accessed December 10, 2008 http://www.mohssurgery.org/2008_medicare_changes.htm

ASMS2 (2008) American Society for Mohs Surgery. Physician training in Mohs Surgery. (Last accessed December 10, 2008) http://www.mohssurgery.org/New/healthCare/physicianTraining.html

Bath-Hextall FJ, Perkins W, Bong J, Williams HC. (2007) Interventions for Basal Cell Carcinoma of the Skin. Cochrane Database System Reviews; (1):CD003412.

Ceilley RI, Del Rosso JQ. (2006) Current Modalities and New Advances in the Treatment of Basal Cell Carcinoma. *International Journal of Dermatology*; 45(5):489-98.

Essner R. (2003) Surgical Treatment of Malignant Melanoma. *Surgery Clinics of North America;* 83(1):109-56.

Han J, Colditz GA, Hunter DJ. (2006) Risk Factors for Skin Cancers: A Nested Case-Control Study within the Nurses' Health Study. *International Journal of Epidemiology;* 35(6):1514-21.

Kaplan AL, Weitzul SB, Taylor RS. (2008) Longitudinal Diminution of Tumor Size for Basal Cell Carcinoma Suggests Shifting Referral Patterns for Mohs Surgery. *Dermatological Surgery*; 34:15–19.

Miller DL, Weinstock MA. (1994) Nonmelanoma Skin Cancer in the United States: Incidence. *Journal of the American Academy of Dermatology*; 30(5 Pt 1):774-8.

Minton TJ. (2008) Contemporary Mohs Surgery Applications. *Current Opinion in Otolaryngology & Head and Neck Surgery*; 16(4):376-80.

NCCN: National Comprehensive Cancer Network. (2008) NCCN Clinical Practice Guidelines in Oncology. Basal Cell and Squamous Cell Skin Cancers. V.I.2008. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nmsc.pdf, (Last accessed October 7, 2008)

Pennington BE, Leffell DJ. (2005) Mohs Micrographic Surgery: Established Uses and Emerging Trends. *Oncology* (Williston Park); (9):1165-71; discussion 1171-2, 1175.

Qureshi AA, Laden F, Colditz GA, Hunter DJ. (2008) Geographic Variation and Risk of Skin Cancer in US Women. Differences between Melanoma, Squamous Cell Carcinoma, and Basal Cell Carcinoma. Archives of Internal Medicine; 168(5):501-7.

Rowe DE, Carroll RJ, Day CL Jr. (1989) Long-Term Recurrence Rates in Previously Untreated (primary) Basal Cell Carcinoma: Implications for Patient Follow-Up. *Journal of Dermatologic Surgery and Oncology*; 15:315–328.

Rowe DE, Carroll RJ, Day CL Jr. (1992) Prognostic Factors for Local Recurrence, Metastasis, and Survival Rates in Squamous Cell Carcinoma of the Skin, Ear, and Lip: Implications for Treatment Modality Selection. *Journal of the American Academy of Dermatology*; 26:976-90.

SEER: (2008) LAG, Melbert D, Krapcho M, Stinchcomb DG, Howlader N, Horner MJ, Mariotto A, Miller BA, Feuer EJ, Altekruse SF, Lewis DR, Clegg L, Eisner MP, Reichman M, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2005, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2005/ , based on November 2007 SEER data submission, posted to the SEER web site, 2008. http://seer.cancer.gov/csr/1975_2005/index.html

Smeets NWJ, Krekels GAM, Ostertag JU, Essers BAB, Dirksen CD, Nieman FHM, et al. (2004) Surgical Excision verses Mohs' Micrographic Surgery for Basal-Cell Carcinoma of the Face: Randomised Controlled Trial. *Lancet*; 364:1766–72.

Snow SN, Madjar DD Jr. (2001) Mohs Surgery in the Management of Cutaneous Malignancies. *Clinical Dermatology*; 19:339–347.

Thissen M et al. (1999) A Systematic Review of Treatment Modalities for Primary Basal Cell Carcinomas. *Archives of Dermatology*; 135: 1177–1183

Appendix VIII

Polysomography for Sleep Apnea

1. Background on Service:

A. Condition(s) Associated with the Service:

Obstructive sleep apnea (OSA) is characterized by repeated episodes of airway obstruction during sleep due to soft tissue collapsing the airway. These episodes manifest as apneas (cessation of breathing) and hypopneas (reductions in breath volume). Obesity and increased neck circumference are two major risk factors. Bothersome symptoms include loud snoring and daytime sleepiness. OSA has been shown to increase the risk of car accidents, hypertension, diabetes, coronary artery disease (CAD), sudden death, and stroke (Young, 2002; Somers, 2008; Flemmons 2002). Approximately 5% of U.S. adults are thought to have symptomatic but undiagnosed OSA. OSA affects up to 15% of overweight or obese adults and is more common among men. Some literature indicates that it is 2 to 4 times more common among patients above age 65, although this is controversial (Young, 2002; Trikalinos, 2007). OSA is generally treated with continuous positive airway pressure (CPAP)(Young, 2002), which includes a mask over the mouth and nose and a blower that continuously provides air under low pressure, keeping the airway open (Somers, 2008).

B. Description of Service:

Polysomnography monitors a variety of physiological parameters during sleep, including sleep stage, breathing and limb movements, oxygen saturation, and cardiac rhythm (ref: Flemmons). It can be performed for a variety of sleep-related disorders (Kushida, 2005), but among Medicare beneficiaries the overwhelming majority (97.3%, in our analysis of a sample of Medicare claims data) are for the diagnosis or management of OSA. Four principal types of sleep studies are relevant to OSA: (1) complete polysomnography, (2) CPAP titration studies, (3) “split night”

studies consisting of complete polysomnography followed by CPAP titration later during the same night, and (4) portable sleep studies. Complete polysomnography includes all of the parameters listed above, is performed in a sleep laboratory and attended by an on-site technician, and is the standard means of diagnosing OSA. CPAP titration is used after diagnosis to adjust the device's air pressure. Portable studies can monitor some to all of the physiologic parameters above, be done at home, and be done without an on-site technician (Flemmons, 2002; Ahmed, 2007; Patel, 2007; American Thoracic Society, 2004).[⌗⌗]

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

Charges per beneficiary for complete polysomnography (CPT 95810) grew from $0.81 to $3.98 between 2000 and 2006 (351%). Charges for polysomnography with CPAP titration (CPT 95811, which includes both CPAP titration alone and "split night" studies) grew from $0.55 to $3.69 (573%). Portable studies were not covered by Medicare during this period.

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: Obesity rates have nearly doubled nationally over the last ten years (CDC Obesity Trends), likely leading to a substantial increase in the prevalence of OSA. Given the more modest changes in the age distribution over this period, the aging population is less of a factor.

Better Evidence of Benefit or Benefit to New Types of Patients: There have been no major new guidelines or changes to the evidence that recommend polysomnography more strongly than before, or that identify benefits of polysomnography for new groups of patients.

[⌗⌗] Medicare distinguishes "polysomnography," which includes sleep staging, from "sleep studies," which do not (ref: ATS Practice Tips).

However, the necessity of laboratory-based polysomnography has come under question in recent years. For diagnosing OSA, a 2007 Agency for Healthcare Research and Quality (AHRQ) Technology Assessment found that portable studies are an acceptable alternative (Trikalinos, 2007), reversing a 2004 assessment commissioned by the same agency (ref: Effectiveness of Portable Monitoring Devices). Some initial research suggests that it might also be possible to diagnose OSA without any sleep study, such as by using a clinical prediction rule or a trial of CPAP (Mulgrew, 2007; Senn, 2006; Trikalinos, 2007; Netzer, 1999; Ahmadi, 2008). For laboratory-based CPAP titration studies, alternatives include auto-titrating CPAP machines and using clinical algorithms (Masa, 2004; West, 2006; Hukins 2005).

New Technology: Not applicable.

B. Diffusion:

Patient Demand: Given the high prevalence of OSA and the fact that most patients do not know that they have it, there is a large reservoir of undiagnosed OSA. Even a modest increase in public awareness of OSA could have a substantial effect on utilization.

Provider Uptake: Reportedly, the number of sleep laboratories unaffiliated with hospitals has increased substantially in recent years, providing more opportunities to perform polysomnography. These independent sleep laboratories are, according to our interviewees, active in promoting their services to primary care physicians.

Once patients are referred to sleep laboratories for evaluation, the sleep laboratory physicians may then order polysomnography, creating a self-referral situation with attendant incentives to increase utilization (Casalino, 2008). Given the rapid growth in polysomnography, the potential role of self-referral may warrant further scrutiny.

C. Financial Factors:

Payment Structure: The profit margin for complete polysomnography and CPAP titration is reportedly generous. Some experts reported that providing follow-up care to patients after they have been diagnosed with OSA was not as profitable and, thus, sleep experts were not spending enough time providing such follow-up. This problematical because intensive follow-up care can improve patient's compliance with CPAP (Hoy, 1999), and CPAP treatment is associated with a reduction in car crashes (George, 2001). According to a 2006 Institute of Medicine Report, "…the primary focus of most existing sleep centers appears to be on diagnosis, rather than on comprehensive care of sleep loss and sleep disorders as chronic conditions. This narrow focus may largely be the unintended result of compliance with criteria for accreditation of sleep laboratories, which emphasize diagnostic standards and reimbursement, for diagnostic testing" (IOM, 2006). New Medicare rules include a requirement for some follow-up after CPAP has been initiated (March 2008 National Coverage Decision).

A second issue promoting the utilization of CPAP titration is that the same current procedural terminology (CPT) code is used for "split night" studies as for CPAP titration alone. This gives providers a strong incentive to provide the diagnostic and titration services on separate nights, and bill for two separate studies rather than one combined study (ATS Provider Tips, 2008)(Patel, 2007).

Medicare Coverage Decisions: During the period 2000 to 2006, Medicare only covered polysomnography, not portable sleep studies. Further, specific findings on polysomnography were required for CPAP to be covered (Ahmed, 2007). Local coverage decisions denying portable studies first occurred as far back as 1994 (CMS Website). In March 2008, a National Coverage Decision authorized certain portable studies, CPAP when portable studies were used for diagnosis, and follow-up assessment after CPAP is initiated (March 2008 National Coverage Decision).

4. Summary:

Several factors together contributed to the rising utilization of polysomnography from 2000 to 2006, including increasing rates of obesity, a large reservoir of undiagnosed patients, the proliferation of independent sleep laboratories, relatively good reimbursement rates, ambiguous CPT codes that create an incentive to perform more tests, and Medicare coverage decisions requiring polysomnography before OSA could be treated.

Section References:

Ahmadi, Negar and Sharon A. Chung, Alison Gibbs, Colin M. Shapiro. (2008) The Berlin Questionnaire for Sleep Apnea in a Sleep Clinic Population: Relationship to Polysomnographic Measurement of Respiratory Disturbance. Sleep Breath; 12(1):39-45.

Ahmed M, Patel NP, Rosen I. (2007) Portable Monitors in the Diagnosis of Obstructive Sleep Apnea. *Chest*; 132(5):1672-7.

American Thoracic Society. (2004) Executive Summary on the Systematic Review and Practice Parameters for Portable Monitoring in the Investigation of Suspected Sleep Apnea in Adults. *American Journal of Respiratory and Critical Care Medicine* 169:1160–1163, 2004

ATS Practice Tips: American Thoracic Society (2008). (Last accessed December 10, 2008) http://www.thoracic.org/sections/career-development/practitioners-page/practice-tips/articles/tip11.html

Casalino LP (2008) The Synthesis Project: Physician Self-Referral and Physician-Owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No. 15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf.

CDC Obesity Trends (Last accessed December 10, 2008) http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/

(CMS) Center for Medicare and Medicaid Services Website (Last accessed December 10, 2008) http://www.cms.hhs.gov/mcd/search.asp?from2=search.asp&

Flemmons WW. (2002) Obstructive Sleep Apnea. *New England Journal of Medicine*; 347:498-504 2002.

George CF. (2001) Reduction in Motor Vehicle Collisions Following Treatment of Sleep Apnea with Nasal CPAP. *Thorax*; 56:508-12.

Hoy CJ, Vennelle M, Kingshott RN, Engleman HM, Douglas NJ. (1999) Can Intensive Support Improve Continuous Positive Airway Pressure Use in Patients with the Sleep Apnea/Hypopnea Syndrome? *American Journal of Respiratory and Critical Care Medicine*; 159:1096-100.

Hukins C. (2005) Arbitrary-Pressure Continuous Positive Airway Pressure for Obstructive Sleep Apnea Syndrome. *American Journal of Respiratory and Critical Care Medicine*; 171: 500-505.

Institute of Medicine. (2006) Sleep Disorders and Sleep Deprivation. An Unmet Public Health Problem. Colten HR, Altevogt BM, eds. Washington, DC: *National Academies Press*

Kushida CA, Littner MR, et al. (2005) Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005. *Sleep* 2005; 28(4):499-521.

March 2008 National Coverage Decision Manual: Chapter 1 Part 4 (Sections 200-310.1) (Last accessed December 10, 2008) http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part4.pdf

Masa JF, Jimenez A, Duran J et al. (2004) Alternate Methods of Titrating Continuous Positive Airway Pressure. A Large Multicenter Study. *American Journal of Respiratory and Critical Care Medicine*; 170: 1218-1224.

Mulgrew AT, Fox N, Ayas NT, Ryan CF. (2007) Diagnosis and Initial Management of Obstructive Sleep Apnea without Polysomnography: A Randomized Validation Study. *Annals of Internal Medicine*; 146:157-66.

Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP (1999) Using the Berlin Questionnaire to Identify Patients at Risk for the Sleep Apnea Syndrome. Annals of Internal Medicine; 131(7):485–491

Patel NP, Ahmed M, Rosen I. (2007) Split-Night Polysomnography. *Chest*; 132(5):1664-71.

Senn O, Brack T, Russi EW, Bloch KE. (2006) A Continuous Positive Pressure Airway Trial as a Novel Approach to the Diagnosis of the Obstructive Sleep Apnea Syndrome. *Chest*; 129: 67-75.

Somers, Virend K, David P. White, Raouf Amin, William T. Abraham, Fernando. (2008) Sleep Apnea and Cardiovascular Disease: J*ournal of the American College of Cardiology*; 52;686-717; originally published online Jul 28, 2008; http://content.onlinejacc.org/cgi/content/full/52/8/686

Trikalinos TA, Ip S, Gowri R, Cepeda S, Balk EM, D'Ambrosio C. (2007) Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome. Rockville MD: Agency for Health Care Research and Quality. http://www.cms.hhs.gov/determinationprocess/downloads/id48TA.pdf

West SD, Jones DR, Stradling JR. (2006) Comparison of Three Ways to Determine and Deliver Pressure During Nasal CPAP Therapy for Obstructive Sleep Apnea. *Thorax*; 61:226-31.

Young T. (2002) Epidemiology of Obstructive Sleep Apnea: A Population Health Perspective. *American Journal of Respiratory and Critical Care Medicine;* 165; 1217–1239

Appendix IX

Procedures for Benign Prostatic Hyperplasia

1. Background on Service:

A. Condition(s) Associated with the Service:

Benign prostatic hyperplasia (BPH) is an enlargement of the prostate that often compresses the urethra and blocks urine flow. Common symptoms include a slow or weak urinary stream, getting up multiple times a night to urinate, and incontinence (Edwards, 2008). BPH is also the most common cause of complete urinary obstruction, an important indication for surgery; however, this affects only a small percentage of men (Edwards, 2008; Selius, 2008). BPH symptoms are a nearly universal consequence of aging, affecting affect more than half of men in their sixties and 90 percent in their seventies and eighties (National Institute of Diabetes, 2006).

For patients who are bothered by moderate to severe symptoms, treatment options include medications and surgical procedures (Edwards, 2008; American Urological Association, 2003). Two classes of medications are effective, particularly when taken together. One dilates the urethra and the other shrinks the prostate over time. The medications can have significant costs and bothersome side effects: respectively, costs are $18-$77 and $95 per month, and side effects include low blood pressure when upright and sexual dysfunction (Edwards, 2008; McConnell, 1998; Roehrborn, 1999; Logan, 2005; Lepor, 2007; McConnell, 2003; Nickel, 1996; American Urological Association 2003).

B. Description of Service:

The standard surgical procedure for BPH has been transurethral resection of the prostate (TURP). This procedure requires general anesthesia, usually involves hospitalization, and can

lead to significant bleeding, urethral strictures, sexual dysfunction, and other complications. However, the procedure is very effective at reducing BPH symptoms and recurrence rates are low (Edwards, 2008; Laurenco, 2008; American Urological Association, 2003).

Over the past decade or so, several less invasive, less risky procedures have been developed and newer ones continue to emerge (American Urological Association, 2003; Lourenco, 2008). The newer procedures use a variety of energy sources, such as electricity, radiofrequency waves, microwaves, lasers and even hot water. These can coagulate the prostate tissue, which later sloughs off into the urine. Alternatively, lasers and electricity can be applied with greater intensity to vaporize or resect the tissue. Common complications often include symptoms of local irritation that last several weeks and complete urinary retention requiring catheterization. Table 1 lists procedures that were commonly used during the 2000 to 2006 period. Several of the procedures are usually done in physician offices (microwave, radiofrequency and laser coagulation) and others in hospital outpatient settings (laser vaporization) (Yu, 2008).

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

There has been a substantial expansion in the use of surgical treatments for BPH, with TURP rates declining and less invasive procedures increasing dramatically. We found charges per Medicare beneficiary for TURPs declined from $2.28 to $1.10 between 2000 and 2006. For the less invasive procedures in Table 1, charges grew from $0.30 to $6.54 between 2000 and 2006. Other authors have reported similar utilization trends in the general population, documenting that, as of 2005, the less invasive procedures account for 57% and TURP accounts for 39% of BPH procedures (Yu, 2008).

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: Although TURP may be too risky for many frail elders (see below), the modest increase in the age of the population over 65 between 2000 and 2006 cannot explain the dramatic increase in the less invasive procedures.

Better Evidence of Benefit or Benefit to New Types of Patients: Whether the evidence for the new procedures' effectiveness is sufficient to justify their use appears to be in the eyes of the beholder. Existing studies primarily describe only short-term outcomes and have major methodological limitations. A 2008 systematic review comparing several of the procedures with TURP found that, in general, they offer similar reductions in BPH symptoms at one year, reduce blood transfusion requirements, and shorten hospital stays. The authors concluded, however, that the existing evidence is insufficient to justify using these new procedures instead of TURP for most patients (Lourenco, 2008). In contrast, a 2006 guideline from the American Urological Association said TURP is "still the benchmark therapy for BPH" but interpreted the evidence for most of the new procedures as sufficient to justify use and left the choice among procedures to the surgeons' discretion (American Urological Association, 2003).

A patient subgroup that is particularly likely to benefit from the less invasive procedures is men who are frail or have co-morbid conditions, due to the lower risk of major complications. The less invasive procedures have grown the fastest among those over 85 and have the highest per-capital utilization rate among those age 75 to 85 (Yu, 2008).

One particular concern regarding the appropriateness of these new procedures is durability. For transurethral needle ablation (TUNA), 83% of patients experience treatment failure by 20 months (Rosario, 2007). For transurethral microwave thermotherapy (TUMT), 10% require additional treatment for BPH symptoms by 5 years (Mattiasson, 2007).

It is unclear whether or not there will be future research that does a better job of evaluating the long-term effectiveness of these new procedures. They are already approved for use and covered under Medicare, and uptake among urologists has been excellent. No private organization, such

as a manufacturer, appears to have an inherent incentive to sponsor a large randomized controlled trial with long-term follow-up, which would be quite costly. The National Institute of Diabetes and Digestive and Kidney Diseases initiated a large, multi-center trial of these less-invasive therapies in 2004 (NIDDK Website); however, the study was terminated in 2006 due to an inability to recruit an adequate sample size (Clinical trials Website). At this time, it appears there are a few short-term studies ongoing (Clinical trials Website; ISRCTNR Website).

B. Diffusion:

Patient Demand: Patients are likely to have strong preferences for the newer procedures over medications and TURP. Some patients may wish to avoid the costs, side effects, and hassles associated with medication therapy, or have found the medications ineffective. At the same time, they may prefer not to undergo an operation that entails significant risks and a several-day hospitalization. Thus, a reservoir of undertreated patients with bothersome BPH symptoms probably explains some of the rapid uptake of the less invasive procedures.

Provider Uptake: There are few barriers to urologists acquiring or obtaining access to the equipment used in the less invasive procedures. This is evidenced by the rapid growth rate as well as a steady shift in utilization patterns from hospital outpatient settings to physician clinics (Yu, 2008). In general, there has been a rapid several-fold increase in the volume of procedures performed in ambulatory surgery centers and physician offices as compared with hospital outpatient surgery centers. This shift appears to be driven by physician ownership or financial stakes in the ambulatory surgery centers and the ability to capture the facility fee in the office setting (Casalino, 2008). As with the other services, the prospect of physician self-referral driving utilization warrants investigation. Further, manufacturers of the devices used during the new procedures have reportedly been very active in disseminating them to urologists, through more than advertising. They are reportedly training urologists to perform the procedures, setting up the equipment in the urologists' offices, and even assisting with the procedures. As one interviewee put it, "the only thing left for the urologist to do is turn the machine on."

C. Financial Factors:

Payment Structure: As can be seen in the table, the relative value units (RVUs) that a urologist can earn for performing the newer procedures are dramatically higher than those for TURP, in part because the new procedures include the office facility component. The reimbursement for the newer procedures is reportedly quite good, while that for TURP has been described as insufficient (Wei, 2008; Donnell, 2002).

Medicare Coverage Decisions: Medicare does provide coverage for the new, less invasive procedures. Local coverage decisions began to appear for some of the procedures starting in 1996 to 1999 (CMS Website).

4. Summary:

A "perfect storm" of clinical factors, patient demand, provider uptake encouraged by device manufacturers, and strong financial incentives for urologists likely explains the switch from TURP to these newer procedures. It is unfortunate that the quality of the evidence for these new procedures is not stronger, and efforts to determine their appropriateness would be greatly facilitated by additional, better quality research.

Section References:

American Urological Association. (2003) Guideline on the Management of Benign Prostatic Hyperplasia (BPH). (Updated 2006). (Last accessed December 10, 2008) http://www.auanet.org/guidelines/main_reports/bph_management/chapt_1_appendix.pdf

Casalino LP. (2008) The Synthesis Project: Physician Self-referral and Physician-owned Specialty Facilities. Robert Wood Johnson Foundation Research Synthesis Report No. 15, available at http://www.rwjf.org/files/research/062408.policysynthesis.physreferral.rpt.pdf.

Clinicaltrials: Minimally Invasive Surgical Therapy for BPH (Last accessed on December 10, 2008) http://www.clinicaltrials.gov/ct2/show/NCT00064649?term=MIST&rank=2

(CMS) Center for Medicare and Medicaid Services Website (Last accessed December 10, 2008) http://www.cms.hhs.gov/mcd/search.asp?from2=search.asp&

Donnell RF (2002) Changes in Medicare Reimbursement: Impact on Therapy for Benign Prostatic Hyperplasia. *Current Urology Reports*; 3: 280. http://springerlink.metapress.com/content/k224463w2m15x268/fulltext.pdf

Edwards JL. (2008) Diagnosis and Management of Benign Prostatic Hyperplasia. *American Family Physician*; 77(10):1403-10.

Helke, Christian, Andreas Manseck, Oliver W. Hakenberg, Manfred P. Wirth. (2001) Is Transurethral Vaporesection of the Prostate Better Than Standard Transurethral Resection? *European Urology*; 39:5

ISRCTNR: International Standard Randomised Controlled Trial Number Register. (Last accessed December 10, 2008) http://www.controlled-trials.com/isrctn/

Lepor H, Williford WO, Barry MJ, et al., for the Veterans Affairs Cooperative Studies Benign Prostatic Hyperplasia Study Group.(2007) The Efficacy of Terazosin, Finasteride, or Both in Benign Prostatic Hyperplasia. *New England Journal of Medicine*; 335(8):533-539.

Logan YT, Belgeri MT.(2005) Monotherapy Versus Combination Drug Therapy for the Treatment of Benign Prostatic Hyperplasia. *American Journal of Geriatric Pharmacotherapy*; 3(2):103-114.

Lourenco, Tania. Robert Pickard, et al. (2008) Alternative Approaches to Endoscopic Ablation for Benign Enlargement of the Prostate: Systematic Review of Randomised Controlled Trials. *British Medical Journal*; 337;a449

Mattiasson A, Wagrell L, Schelin S, et al. (2007) Five-Year Follow-Up of Feedback Microwave Thermotherapy versus TURP for Clinical BPH: A Prospective Randomized Multicenter Study. *Urology*; 69(1):91-96.

McConnell JD, Bruskewitz R, Walsh P, et al., for the Finasteride Long-Term Efficacy and Safety Study Group. (1998) The Effect of Finasteride on the Risk of Acute Urinary Retention and the Need for Surgical Treatment among Men with Benign Prostatic Hyperplasia. *New England Journal of Medicine*; 338(9):557-563.

McConnell JD, Roehrborn CG, Bautista OM, et al., for the Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. (2003) The Long-Term Effect of Doxazosin,

Finasteride, and Combination Therapy on the Clinical Progression of Benign Prostatic Hyperplasia. *New England Journal of Medicine*; 349(25):2387-2398.

National Institute of Diabetes and Digestive and Kidney Diseases. (2006) Prostate Englargement: Benign Prostatic Hyperplasia. National Kindey and Urologic Diseases Information Clearinghouse. NIH Publication No. 07-3012. June 2006. http://kidney.niddk.nih.gov/Kudiseases/pubs/pdf/ProstateEnlargement.pdf

Nickel JC, Fradet Y, Boake RC, et al.(1996) Efficacy and Safety of Finasteride Therapy for Benign Prostatic Hyperplasia: Results of a 2-Year Randomized Controlled Trial (the PROSPECT study). PROscar Safety Plus Efficacy Canadian Two Year Study. *Canadian Medical Association Journal*; 155(9):1251-1259.

NIDDK: Minimally Invasive Surgical Therapies Treatment Consortium for BPH (Last accessed on December 10, 2008) http://www.niddk.nih.gov/patient/mist/mist.htm

Roehrborn CG, Boyle P, Bergner D, et al., for the PLESS Study Group. (1999) Serum Prostate-Specific Antigen and Prostate Volume Predict Long-Term Changes in Symptoms and Flow Rate: Results of a Four-Year, Randomized Trial Comparing Finasteride versus Placebo. *Urology*; 54(4):662-669.

Rosario, Derek J, Joshua T. Phillips and Christopher R. Chapple.(2007) Durability and Cost-Effectiveness of Transurethral Needle Ablation of the Prostate as an Alternative to Transurethral Resection of the Prostate When Alpha-Adrenergic Antagonist Therapy Fails. *Journal of Urology*; 177(3):1047-51

Selius BA, Subedi R. (2008) Urinary Retention in Adults: Diagnosis and Initial Management. *American Family Physician*; 77(5):643-50.

Wei J. (2008) Editorial Comment. *Journal of Urology*; 180(1):245.

Yu X, Elliott SP, Wilt TJ, McBean AM. (2008) Practice Patterns in Benign Prostatic Hyperplasia Surgical Therapy: The Dramatic Increase in Minimally Invasive Technologies. Journal of Urology; 180(1):241-5;

Appendix Table 1: Surgical Procedures Commonly Performed for BPH Symptoms

Procedure Name	Description (Edwards, 2008; American Urological Association, 2003; Lourenco, 2008; Helke, 2001)	CPT code	Charges per Beneficiary			RVUs in 2006 (Change 2000-2006)
			2000	2006	Change	
Transurethral Resection of Prostate (TURP)	The prostate is surgically removed via a scope inserted in the urethra	52601	$2.28	$1.10	- 52%	MD only 18.33 (-10%)
Common Less-Invasive Procedures						
Laser Vaporization of Prostate	Laser used to vaporize prostate tissue	52648	$0.07	$0.76	949%	MD + Office 86.13 (+358%)
Laser Enucleation of prostate	Laser used to resect prostate tissue	52648 (2008: 52649)				
Transurethral electrovaporization of prostate (a.k.a. transurethral vaporization, TVP)	Roller electrode is passed over the prostate to vaporize prostate tissue	52648				
Transurethral vaporesection (a.k.a. transurethral vaporizing resection of the prostate, TUVRP)	Large electrode is used to vaporize and resect prostate tissue	52648				
Laser Coagulation of Prostate (a.k.a. visual laser ablation of the prostate [VLAP])	Laser used to coagulate prostate tissue	52647	$0.06	$0.71	1,093%	MD + Office 85.22 (+443%)
Transurethral needle ablation (TUNA)	Radiofrequency waves used to coagulate prostate tissue	53852	$0.04	$1.02	2,738%	MD + Office 99.60 (+562%)
Transurethral microwave thermotherapy (TUMT)	Microwaves used to coagulate prostate tissue	53850	$0.13	$4.05	2,914%	MD + Office 104.44 (+537%)

Appendix X

Spinal Injection Procedures for Back Pain

1. Background on Services:

A. Condition(s) Associated with the Service:

Low back pain without sciatica, stenosis or severe spinal deformity is common, with a reported point prevalence rate as high as 33% (Skovron, 1994) and a one-year prevalence as high as 73%. (Cassidy, 1998). Acute low back pain usually resolves in several weeks although recurrences are common. An estimated 7% of patients develop chronic or persisting low back pain, that is, pain that persists more than six weeks after onset which is our interest for this study. (van Tulder, 2007; Carragee, 2005)

A major clinical differentiation in low back pain evaluation and treatment is the presence or absence of specific complicating factors: significant radicular (nerve root) involvement of the lower extremities, i.e., sciatica, or other specific neurological signs and symptoms, e.g., urinary incontinence in spinal stenosis or spinal structural instability, such as spondylolysis. In these situations there is good evidence to support epidural injections or surgical interventions.

The majority of low back pain patients do not have complicating factors. Pain is “non-specific” (general) in about 85% of people; about 4% of people with low back pain in primary care have compression fractures, about 1% have a tumor, between 1-3% have a prolapsed intervertebral disk, and the rest of a variety of other conditions (van Tulder, 2007).

As discussed more fully in the section on computed tomography (CT) and magnetic resonance imaging (MRI) scans of the lumbar spine, patient symptoms, underlying pathology, and radiological appearances are poorly correlated. In the elderly, in particular, it is common to find

in symptomatic and asymptomatic patients similar radiologic findings of disk degeneration, annular disruption, and end-plate changes. (Carragee, 2005).

Nor do most patients have surgically correctable problems. Our interest here is in the use of spinal injections for these patients. Although their conditions may be less serious because of the lack of nerve involvement, nevertheless these patients may have severe, even disabling pain. For these patients, injection procedures and neuroablation procedures have proliferated.

B. Description of Service:

We focused on the non-invasive, injection procedures and the imaging test that complements them, specifically the code for fluoroscopy, which is used to guide the injection or radiofrequency needle tip to the desired location on the spine. Considered here are lumbar or sacral epidural and subarachnoid injections, paravertebral facet joint or facet joint nerve injections, and facet joint nerve ablations, all conducted under fluoroscopic guidance. Injections usually provide either corticosteroids or anesthetic agents to the desired location. Radiofrequency facet joint neuroablation is a minimally invasive procedure which coagulates and inactivates the nerves to the joints. This technique primarily involves coagulating the nerves that transmit pain signals from the joints, using highly localized radiofrequency energy at the tip of the needle.

The resources involved with these services are low-tech – essentially straight-forward fluoroscopic guidance equipment and a physician with skill at injections. There is little potential harm associated with these non-invasive injections and ablation procedures so they are able to be provided in many ambulatory settings. (According to the Relative Value Update Committee (RUC) database, the plurality of these procedures are performed in physician offices. Hospital outpatient departments and ambulatory surgery centers are also common sites for performance)**.**

2. Observed Growth in Charges per Medicare Beneficiary From 2000 to 2006:

A number of different current procedural terminology (CPT) codes represent the various procedures considered here. Growth rates were remarkably high for the group. For example, per-beneficiary charges for transforminal epidural injection into the lumbar or sacral spine (CPT 64483) increased from $0.18 to $2.14 (1111.72%) and facet joint or facet joint nerve injection in the lumbar or sacral region (CPT 64475) increased from $0.18 to $1.89 (947.4%). The per-beneficiary charges for the accompanying fluoroscopic guidance radiology procedure (CPT 76005) increased from $0.13 to $1.68 (1229.9%). All together, charges for this set of procedures increased from $1.72 to $15.03 (774.0%)

3. Potential Reasons for Growth:

A. Clinical Factors:

Epidemiologic Trends: As already noted, chronic low back pain is very common and is likely to increase with increases in obesity. However, during the relatively short period reviewed in this study, there was no reason to attribute more than marginal increases in volume growth to such trends.

Better Evidence of Benefit or Benefit to New Types of Patients: There is virtually no evidence that the various injection and neuroablation procedures improve chronic low back pain in people without sciatica. A British Medical Journal (BMJ) evidence review concludes, "We don't know whether epidural steroid injections or local injections with corticosteroids and local anesthetic improve chronic low back pain without sciatica. Facet joint corticosteroid injections may be no more effective than placebo at reducing pain" (Samantra, 2004).

A recent review concluded that "in randomized clinical trials, injections of glucocorticoid or anesthetic agents into the epidural space, lumbar discs, lumbar facets and trigger points have not improved outcomes in patients who have chronic low back pain without radiculopathy (Carette, 1991; Nelemans, 2001; Khot, 2004). The review further cites studies showing that

radiofrequency ablation of the small nerves to the facet joints ("facet rhizotomy") was ineffective or showed slight, short-term improvement (Leclaire, 2001; van Kleef, 1999).

A problem with reliance on evidence in this area is that very few randomized trials have been conducted. Accordingly, there are various treatment approaches in use and little clinical evidence to guide treatment options. Indeed, even among our experts there were significant differences of opinion, with one calling most of the frequently performed and growing injection and neuroablation procedures "bogus," while others thought that these procedures provided temporary relief in large numbers of patients and were therefore worth trying in most cases of severe back pain.

The latter experts agree that the formal evidence is not strong, but that accumulated clinical experience demonstrates effectiveness of some of these interventions. They agreed that there was a lack of definitive clinical trial data for some of the common uses but were more impressed by their experiences of benefits, particularly from facet joint procedures. In general, they agreed with the literature conclusions that epidural injections by either approach – interlaminar or transforaminal – were not beneficial in the absence of nerve root involvement. However, they were much more positive about facet joint injections and neuroablation procedures and believed that empirically trying out the intervention on affected patients to see if they benefit with pain reduction, that is, performing a "therapeutic trial," is an effective way to diagnose treatable facet syndromes.

New Technology: Not applicable.

B. Diffusion:

Patient Demand: There was agreement that patients are continually seeking alternatives to the most conservative approaches to treating chronic back pain including exercise, behavioral therapy, and use of analgesics and muscle relaxants. Experts agreed that the proliferation of pain

clinics has been a response to this demand. Contributing to greater demand has been the response of generalist physicians caring for patients with back pain. "More primary care doctors are frustrated with taking care of pain patients and they send them off to specialty clinics."

Provider Uptake: The two main expert skeptics of the procedures assert that the large increase in Medicare claims for these services has occurred because of the proliferation of "pain clinics" with most of the injectors being pain specialists, primarily anesthesiologists and physical medicine and rehabilitation (PM&R) physicians. They ascribe the increase directly to commercial interest stimulated by the pain clinic phenomenon and the general growth in public expectations that for any problem medical science has a solution, usually a technologically-based one. The two other experts agree that the pain clinics are largely responsible for the main provider uptake of these services but take a more positive view, arguing that they fill a need.

C. Financial Factors:

Payment Structure: There was agreement among our experts that Medicare and commercial insurance payment systems promote injections and related interventions because of the relatively more generous reimbursement from procedural services compared to evaluation and management (E&M) services. Indeed, the experts thought that pain patients often had psychological issues that deserved exploration and counseling but that because the reimbursement for evaluation and management is relatively low, many pain specialists rely inordinately on the higher reimbursed injection procedures. Also, all agreed that fluoroscopy to correctly position needles for injections was an absolute requirement of these injection and ablation procedures, thereby generating another technological services that was well reimbursed compared to E&M services.

Medicare Coverage Decisions: There have not been recent National Coverage Decisions related to these services.

4. Summary:

There is a very little evidence base on which to judge appropriateness of various injection and related procedures for chronic low back pain. However, even the most liberal application of available evidence suggests substantial inappropriate use of these long-standing, "low tech" interventions. There does not appear to be any new clinical information – from clinical trials or elsewhere – to explain the huge volume increases. Rather, demand has increased, with all of our experts agreeing that the new pain management industry, based around pain centers, has been largely responsible for both helping induce and respond to this demand. However, the experts did not agree whether this new demand was warranted – again because of the difficulty inherent in doing research on pain and the general dearth of good clinical trials in this area. Reimbursement for the injection and ablation codes that have soared was relatively generous and certainly generous in comparison to evaluation and management services that should play an important role in assisting patients with chronic pain.

Section References

Carette S, et al, (1991) A Controlled Trial of Corticosteroid Injections into Facet Joint for Chronic Low Back Pain. New England Journal of Medicine; 1325:1002-7.

Carragee EJ. (2005) Persistent Low Back Pain. New England Journal of Medicine; 352:1891-8.

Cassidy JD, Carroll LJ, Cote. (1998) The Saskatchewan Health and Back Survey: the Prevalence of Low Back Pain and Related Disability in Saskatchewan Adults. *Spine*; 23:1860-66.

Khot et al, (2004) The Use of Intradiscal Steroid Therapy for Lumbar Discogenic Pain: A Randomized Clinical Trial. *Spine*; 29:833-6.

Leclaire et al, (2001) Radiofrequency Facet Joint Denervation in the Treatment of Low Back Pain: A Placebo-Controlled Clinical Trial to Assess Efficacy. *Spine*; 26:1411-6.

Nelemans et al, (2001) Injection Therapy for Subacute and Chronic Low Back Pain. *Spine*; 26:501-15.

Samantra, Ash, Jo Samantra, (2004) Epidural Injection of Steroids Effective for Low Back Pain? *British Medical Journal;* 328: 1509-1510

Skovron ML, et al. (1994) Sociocultural Factors and Back Pain: A Population-Based Study in Belgian Adults. *Spine*; 19:129-37.

van Kleef et al, (1999) Randomized Trail of Radiofrequency Lumbar Facet Denervation for Chronic Low Back Pain. *Spine*; 24:1937-42.

van Tolder M and Koes B. (2007) Low Back Pain (Chronic) 349-351 in *British Medical Journal: Clinical Evidence Handbook* (London: BMJ Publishing Group, Summer 2007).