Evaluating Approaches for Adoption of Medical Technologies

Sponsored by the Society of Actuaries' Health Section

Prepared by
Robert D. Lieberthal
Tony Amos
Jessica Lopatto
Jefferson University of Population Health

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Foreword

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POG members:

Andie Christopherson

Lijia Guo

Song-Song Liao

Jed Linfield

John Ninomiya

Sandee Schuster

SOA project coordinators:

Barbara Scott

Steven Siegel

Jefferson School of Population Health:

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Executive Summary

An Actuarial Approach to Medical Technologies

Prologue

Health care is a major industry in the United States, accounting for $2.7 trillion in spending, or 17 percent of the country's gross domestic product (GDP) (Fineberg 2012). The cost of the health care industry and the outcomes it has produced have led to the following question: Are we getting value for money? Despite spending more than any other country on health care, the United States does not achieve the best outcomes on many measures of population health, which suggests that the answer is often "no" (Davis, Schoen & Stremikis 2010).

The goal of improving value in health care has motivated a major change in financing of health care in the United States. Reimbursement for care is moving from the historical, fee-for-service-based payment system, to models of care based on bundling, capitation, and other managed care models. The ultimate goal of this new system is to pay for value rather than for volume (Schroeder & Frist 2013). In order to shift to a system of paying for value, health insurers will need to become more engaged in the process of determining what is valuable in health care.

What Is a Medical Technology?

We refer to any product or service that a patient receives in a health care setting as a "medical technology." We use the term "technology" (sometimes also referred to as an "intervention") in an economic sense, meaning a process that combines capital and labor (inputs) to achieve a desired end (output) (Varian 1992). Health care technologies include a wide variety of products and services, from a visit in a doctor's office for an annual checkup to chemotherapy delivered to a patient with cancer. When combined, these inputs can achieve outputs in terms of improved health, such as extending life span, preventing heart attacks, or ameliorating pain. By defining medical technologies in this way, the results of the analysis of a particular technology can then be utilized within the reimbursement system to determine how much to pay for care.

Methods for Evaluating Medical Technologies

There are a number of existing methods for evaluating medical technologies. We focused primarily on the field of health economics and outcomes research (HEOR), as HEOR is the discipline that

is concerned with determining the value of medical technologies. In other words, once a medical technology has been proved safe, efficacious and effective, its value can be analyzed, especially in comparison to existing medical technologies. Promoting value in health care means utilizing HEOR evidence to encourage the utilization of higher-value technologies and reduce the utilization of technologies with a low value.

Evaluating medical technologies from an actuarial perspective

The purpose of this project was to create a tool that would allow actuaries to derive an understanding of the evidence for medical technologies that are provided through health plans. Actuaries have a major role in financial aspects of health plans, such as pricing. Thus, strategies to promote cost containment and increase value in health care are a part of the work that actuaries do, especially when such strategies include changes to reimbursement. Moving toward value in health care involves combining economic evidence about medical technologies with information specific to a health plan. While most of the evidence required for actuaries to promote value in health care already exists, actuaries may require assistance in accessing and using this evidence in their practice.

Results of the Project

Educational material

One main product of our project was educational and background material regarding the evaluation of medical technologies tailored for actuaries. Sections I through III provide this educational material. We created an overview of how medical technologies are evaluated, how they are adopted for reimbursement in health plans, and how the movement toward value in health care calls for actuaries to consider how value can be a part of changes in health care financing. We explain the motivation for evaluating new and existing medical technologies and review existing methods for examining medical technologies to determine their relative value.

Structured tool

We created a structured tool to allow actuaries to organize the existing body of evidence, or evidence base, for any medical technology. The tool applies to a specific technology and indication for its use, and allows actuaries to collect pertinent information about new technologies in one place. The tool has four main sections:

1. Classifying the technology—This section creates a location to collect basic information about the technology and indication for its use, and where it might fit within existing benefits for a health plan.

2. Evidence base—This section allows actuaries to summarize the evidence as to the health outcomes of a technology and its cost, as well as evidence about cost-effectiveness, i.e., value. It also provides a structured mechanism for actuaries to assess the strength of the evidence collected, as well as its support for technology adoption.

3. Applying the evidence—This section allows actuaries to apply the evidence collected in the evidence base section to their particular health plan. It allows actuaries to understand how the general value proposition for a technology applies to their plan in particular.

4. Feedback loop to assess performance—The final section of the tool facilitates an ongoing assessment of a technology. It allows for a forward-looking view of a technology, such as when additional data might become available, to assess how the expected performance indicated in the evidence base compares to actual experience in a health plan.

Implications for the evaluation of medical technologies

As far as we are aware, actuarial involvement in HEOR has been limited. A recent actuarial analysis of lung cancer screenings by actuaries was described as the "first of its kind" (Pyenson, Sander, Jiang, Kahn & Mulshine 2012). HEOR researchers, practitioners, and others who are interested in influencing individuals in health plans with a financial role may also be able to use the tool we have provided to understand how actuaries view evidence regarding medical technologies. Our tool could be particularly helpful with the need to communicate evaluations (studies) of medical technologies to a wider audience, which has been identified as a major area of continued improvement for HEOR as a discipline.

In conclusion, as the focus on reimbursement for value rather than volume grows in importance, increased actuarial awareness of the process for evaluating medical technologies can be one way forward for implementing changes in the U.S. financing and reimbursement system. Our research is part of that improvement process, as it serves to educate actuaries, increase their knowledge of the discipline of HEOR, and to highlight their perspective on medical technologies.

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I. Background

A. Adopting Medical Technologies

Innovation is the watchword of the U.S. health care system. Health care in the United States features care that is both cutting edge and that features a stream of new ways to improve health. Any medical technology has a long path between conception and implementation in the health care system. In this project, we consider the "last mile" along this pathway. When a new medical technology is developed, how does it ultimately reach the patient? For the majority of those in the United States with health insurance, any health care product or service is paid for as a covered benefit by their health insurance plan. As a result, health plans play a "gatekeeper" role to a certain extent, determining the scope of plan benefits, applying those benefits to categories of health care products and services, and approving specific benefits within the design of a given health plan.

In the past, the gatekeeper role was minimal because health care was generally financed under a fee-for-service/product system. Under this system, a fee plus a profit component was built into the payment (Cleverley, Song & Cleverley 2010). Increasingly, and particularly under the Affordable Care Act (ACA) legislation, goods and services are bundled into case or episode-of-illness payments (Patient Protection and Affordable Care Act 2009). As a result, health care decision makers must make judgments about the mix of goods and services that is most worthwhile in delivering favorable outcomes for patients while maintaining fiscal viability. This process has changed health insurance, primarily through the rise of managed care, which has supplanted the longstanding indemnity model for health insurance. Managed care now includes payment mechanisms that are augmenting or replacing fee-for-service with the "bundled payment" perspective, including pre-specified per-member-per-month (PMPM) reimbursements and episode-of-care payments tied to a specific condition.

B. Approaches to Evaluating and Adopting Medical Technologies

This change to health care financing mechanisms is part of a broader focus on promoting value throughout the U.S health care system. To an extent, managed care reflects the move to higher value, such as when higher value care is more likely to be reimbursed. However, the managed care perspective can conceptualize cost in a way that is distinct from the way that medical technologies are evaluated. For example, the methodologies for evaluating medical technologies, such as cost-effectiveness, usually cover an extended period—often a lifetime. On the other hand, managed care assessments such as

PMPM are often finite assessments based on costs during a plan year that are somewhat unrelated to cost-effectiveness analysis. Actuaries who wish to incorporate the evidence related to the value of medical technologies into their practice require greater knowledge of methodologies for evaluating medical technologies. This knowledge can also stimulate collaboration with experts in such methodologies, since most actuaries will not become experts in this field.

Our project points to ways that the actuarial skill set can be applied to the evaluation process. We developed material to facilitate actuarial education in the methods that are used to justify the benefits of new and existing medical technologies. In other words, when a patient receives a drug, or undergoes a medical procedure or a laboratory test, the value of that drug, procedure or test has been measured ahead of time. However, the results of those measurements, and how they are performed and communicated, may not be targeted to an actuarial audience. For the purposes of this project, we provide educational material and a structured tool that can be applied to understanding the value of any medical technology. In other words, as long as a patient receives a product or service in a health care setting, we refer to it in the most generic sense, as a "medical technology."

The term "technology" (sometimes also referred to as an "intervention") has a specific economic meaning as a process that combines capital and labor (inputs) to achieve a desired end (output) (Varian 1992). Health care technologies include a wide variety of products and services, from a visit in a doctor's office for an annual checkup, to chemotherapy delivered to a patient with cancer. When combined, these inputs can achieve outputs in terms of improved health, such as extending life span, preventing a heart attack, or ameliorating pain. Our broad definition of medical technologies naturally segues into introducing and explaining the field of health economics and outcomes research (HEOR) as a key stakeholder that generates and interprets the evidence to be used for the adoption of medical technologies.

HEOR is the discipline that is concerned with determining the value of medical technologies. The methods, findings and literature of this field allow for the determination of the value of a medical technology. As with any discipline, the field has grown through the efforts of researchers and practitioners working in health care industries, academia, and the government in order to determine best practices for evaluating medical technologies, as well as the practical work of performing evaluations and using the results in practice. In the case of HEOR, the government is also an important party, since government regulators play an important role in oversight of the safety and efficacy, as well as health economic information, concerning many types of medical technologies. In other words, the

government regulates the flow of information regarding the value of drugs and medical devices, including information for managed care companies (Neumann 2009). The government also plays an important regulatory role related to other types of interventions—for example, through the licensing of physicians who are trained to deliver medical care. These laws and regulations, especially those involving the Food and Drug Administration (FDA), bind the actions of both manufacturers and providers in developing and using health technology assessment (HTA) evidence.

C. Theoretical Foundations for HEOR

We proceed with a brief introduction to the theoretical foundations of cost-effectiveness analysis before presenting the specific motivation and examination of guidelines and tools for HEOR. Cost-effectiveness analysis "...evolved as a practical response to the need to allocate limited resources for healthcare..." (Garber, Weinstein, Torrance & Kamlet 1996) with practical guidelines that are based on economic theory. At its core, cost-effectiveness is based on the economic principle of "marginal analysis." Marginal analysis conceptualizes any technological improvement based on whether it is more valuable than existing technologies given the difference in cost, which is the essence of cost-effectiveness analysis.

In addition to theoretical considerations, many of the questions that motivate cost-effectiveness analysis are eminently practical. For example, market prices are generally used to account for the cost of care in a cost-effectiveness study. This practical choice is also motivated by economic theory that market prices reflect the true cost of resources. As another example, people see time spent waiting for the doctor as being inferior to time spent at work or with their family, so economic methods should account for that preference when calculating the cost of an intervention.

In this context of medical technologies, cost-effectiveness analysis involves collecting and comparing the cost of, and effects of, different health interventions. In comparing treatment A to treatment B, where treatment B is more expensive and more effective,[1] the three questions posed by cost-effectiveness analysis are: 1) How much more effective is treatment B? 2) How much more expensive is treatment B? 3) What is the value of the incremental (additional) effectiveness gained by

[1] If a treatment is less expensive and more effective, then it is a "dominant treatment," and no decision analysis is required. It is also possible to introduce a treatment that is less effective and less costly, but in reality this seldom occurs in the U.S. health care system (Pauly 2008).

implementing treatment B given its incremental (additional) cost relative to treatment A? Effectiveness is judged based on outcomes. The outcome may be reduction in mortality; reduction in morbidity, such as heart attacks; or a surrogate end point, such as improved cholesterol or blood pressure. Lower cholesterol is not a primary outcome in and of itself, but using risk equations may generate estimates of lower morbidity and/or mortality rates that can be translated into cost estimates in lieu of the direct measures for morbidity or mortality in a properly designed clinical trial. Cost is based on pricing and reimbursement, which calls for the expertise encompassed in the actuarial skill set.

In comparing treatments, it is important to "… compare interventions whose benefits are measured in the same units of effectiveness" (Garber et al. 1996). One technique used to put cost-effectiveness analysis on a common ground for all treatments is the "quality adjusted life year" or QALY. QALYs are important if one wishes to examine and compare the cost-effectiveness of an intervention that improves the quality of life, such as a migraine or depression treatment with a treatment expected to influence heart attacks or deaths (Hirth, Chernew, Miller, Fendrick & Weissert 2000). It is important to note that it is an open question in the HEOR literature as to whether technologies designed for such different disease states can be compared using QALYs or any other methodology. This open question involves many additional considerations in terms of evidence beyond the level of what we utilized in this project, and thus is beyond the scope of this report.

II. Motivation

A. Evaluating Medical Technologies

An evaluation of a medical technology and a decision about technology adoption might take place in two basic scenarios. The first scenario is one where a new technology is introduced to address a specific disease and/or indication for its use. In this scenario, a health plan would need to examine clinical and economic evidence about a new technology in order to determine whether or not to adopt it as a covered benefit of the health plan. The new technology would be evaluated relative to its comparators, meaning competing technologies that address the same disease state or indication. Thus, the introduction of a new technology would require reviewing the evidence about both the new technology and any comparators. For a new technology, the evidence may be related mainly to the results of clinical trials. For comparators, both clinical trial data and subsequent "real-world" data

generated through the use of the product in a health care setting, paid for by health plans, may be available.

Comparing the overall value of all options using evidence on value would allow a health plan to determine whether or not to cover the new technology (i.e., adoption), the reimbursement for the new technology (i.e., price the plan is willing to pay), potential changes to reimbursements for existing technologies, and the degree of plan member cost sharing, if any, through copayments, coinsurance, and deductibles. In this case, actuaries would have a role in adjusting health plan pricing to reflect the new set of available technologies, as well as making adjustments to plan design as necessary. Depending on the health plan setting, actuaries could also be a key stakeholder in decisions regarding adoption in addition to their roles in pricing and reimbursement.

The second basic scenario is one where a plan is motivated to review earlier coverage decisions for a specific disease and/or indication. In this case, the same evidence would be needed as in the scenario where a new technology spurs this comparison: all available comparators should be considered in terms of their relative value. One key difference in a technology review scenario might be in terms of what evidence is available about comparators. There may be more evidence on all comparators because the longer any technology is available for use, the more time and data will be available for researchers to study "real-world" evidence about how a technology is working. In addition, in the scenario of reviewing a prior coverage decision, a health plan will have access to its own data about how a specific technology or group of technologies is working in the specific context of the health plan. One downside of the technology review scenario is that any evidence generated by clinical trials may have a tendency to be less current, since one of the main motivations for producing evidence through clinical trials is to facilitate and justify the adoption of new technologies.

We see three main ways that both scenarios apply to the actuarial role in the design and management of health plans. First, actuaries have a major role in pricing benefits, so changes in a health plan's costs relating to the replacement of an existing technology with a new technology, or based on a review of existing coverage under a health plan, require actuarial expertise. Most new technologies offer improved clinical outcomes over the existing technology. In general, improving value means finding ways to improve outcomes or to obtain outcomes available from current technologies at a reduced cost. New technologies generally change the cost of treatment for the given indication, both overall as well as for the categories of cost within types of health plans (medical costs vs. drug costs). Value means considering cost closely for any medical technology, whether in the scenario where a new

technology is introduced or where existing coverage decisions are reviewed. Evaluating any medical technology means answering several important questions, generalizable to any scenario where medical technologies are evaluated, which constitute the core of cost-effectiveness analysis and related methods for determining the value of medical technologies:

- What is the value of a new or existing technology compared to the option of leaving the condition untreated?
- What is the value of each technology relative to all available comparators?
- What is the value of a new technology when compared to similar new technologies being introduced concurrently?
- How does the general value of a medical technology differ across different health plans that may cover different populations?

B. Application of HEOR to the Evaluation of Medical Technologies

The questions we pose are ones that the field of HEOR attempts to answer. Some of the questions posed, especially the one regarding value within health plans, would benefit from additional actuarial exploration. Thus, our main motivation is to bring the field of HEOR to actuaries, in order to educate them and allow them to use HEOR findings in setting managed care reimbursements. Pricing often includes the need to determine how many individuals will switch treatments when a new technology is available or when the member's financial responsibility for a particular technology changes. It also includes the costs and outcomes associated with the "woodwork effect," whereby the introduction of a new technology "activates" some previously untreated patients to have their condition diagnosed and to initiate treatment with the new technology. Finally, many plans separate costs by medical vs. drug costs, whereby plans only pay for one of these two types of costs, or are "carve-outs" for services such as behavioral health. Actuaries with a greater understanding of how medical technologies are evaluated could use this knowledge both for existing business problems they deal with in practice, and in order to have a greater role in technology evaluation.

Given the goal of participating in the adoption of medical technologies, we sought to help actuaries learn more about HEOR and to give them a way to conceptualize the evaluation of medical technologies that is congruent with the discipline of HEOR. We accomplish these broad goals through

two steps. First, we detail elements of the evaluation of medical technologies and the existing methods to perform such evaluation. Second, we describe a structured tool that we developed to allow the information regarding the value of a medical technology to be compiled and organized by actuaries. A structured tool means a list of questions, organized by section, that elicits information regarding new and existing medical technologies. Further use of this evidence can then be undertaken by actuaries using their preliminary findings to get information that is more detailed on the particular medical technology from practitioners with clinical expertise.

III. Existing Methods for HEOR

A. ISPOR Guidelines

One guideline we reviewed for the practice of HEOR was the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Consolidated Health Economic Evaluation Reporting Standards (CHEERS) on the reporting of HEOR evidence. ISPOR is the largest educational and scientific organization devoted to the outcomes of medical technologies. As a result, ISPOR has done a great deal of work creating guidelines for performing studies evaluating medical technologies. In 2009, an ISPOR task force published a report on quality improvement issues and initiatives in cost-effectiveness research. Cost-effectiveness research is a methodology to merge information about the health outcomes of medical technologies with information about their cost, in order to assess the overall value of new and existing medical technologies. The task force created a guideline checklist that allows for the evaluation of the quality and rigor of studies evaluating medical technologies (Husereau, Drummond, Petrou, Carswell, Moher, Greenberg, Augustovski, Briggs, Mauskopf & Loder 2013; Husereau, Drummond, Petrou, Carswell, Moher, Greenberg, Augustovski, Briggs, Mauskopf & Loder, on behalf of the ISPOR Health Economic Evaluation Publication Guidelines—CHEERS Good Reporting Practices Task Force 2013).

The task force also reported on areas of improvement in HEOR. The report highlighted uncertainty of results, the highly specialized nature of cost-effectiveness research, and the inaccessibility of research, which is often published in highly technical journals. Task force recommendations included allowance for an assessment and communication of the degree of uncertainty in any assessment, improvement in guidelines, increased rigor of publications, and the provision of better education concerning methodologies and publications as the path to quality improvement in cost-effectiveness

research (Husereau, Drummond, Petrou, Carswell, Moher, Greenberg, Augustovski, Briggs, Mauskopf & Loder, on behalf of the ISPOR Health Economic Evaluation Publication Guidelines—CHEERS Good Reporting Practices Task Force 2013). This task force also created a checklist concerning the proper performance of cost-effectiveness studies that is well beyond the needs of actuaries. As studies of cost-effectiveness continue to be performed, those interested in these methodologies and how they are refined can use the ISPOR guidelines as a framework for best practices. Those issues are generally beyond the scope of this report.

B. AMCP Formulary Guidelines

Another guideline we reviewed was the Academy of Managed Care Pharmacy (AMCP) dossier for formulary submissions. AMCP is the professional organization of pharmacists working in a managed care setting. We reviewed the most recent major update of the dossier, AMCP dossier 3.1, and version 3.0 on which it is based (FMCP Format Executive Committee 2010; Academy of Managed Care Pharmacy 2012). The role of the AMCP dossier is to respond to unsolicited requests for information on "...consideration of a new product, new indication, or new formulation of an existing product" when that product is being considered for a formulary, meaning that it is a drug or a device. The dossier consists of a structured format that standardizes evidence regarding the outcomes and costs of a drug under consideration by a managed care plan, communicating value and "making evidence and rationale supporting all choice(s) more clear, transparent and evaluable by decision makers"(FMCP Format Executive Committee 2010).

Evidence in dossiers is meant to be a confidential communication between the manufacturer and the health system. Health plans that wish to know more can solicit this evidence directly from the manufacturer. As these communications are confidential, we are unable to comment on the dossiers or specific communication regarding specific products for specific health plans.

The AMCP dossier is a resource for the assessment of drugs and devices, especially concerning issues of value. The AMCP dossier does not address other medical technologies that are not drugs or devices, such as a new type of non-pharmacologic therapy for those with depression. As the AMCP format is designed to support the pharmacy and therapeutics (P&T) committee or other health technology assessment committees of a health plan, actuaries may find its clinical orientation to be a barrier to understanding the evidence. It is important to note that actuaries who wish to learn more can direct their questions toward the P&T committee and similar bodies at the health plans they work for.

C. Other Sources that Evaluate Medical Technologies

Another source that evaluates and comments on the appropriateness of cost-effectiveness studies is the Tufts Cost-Effectiveness Analysis (CEA) Registry. The Tufts CEA Registry (https://research.tufts-nemc.org/cear4/) is primarily academic in nature, and summarizes studies published in the peer-reviewed literature (scientific and medical journals) regarding the cost-effectiveness of certain medical technologies. For example, typing "lung cancer screening" into the registry search tool brings up two cost-effectiveness studies related to this intervention (Tufts Center for the Evaluation of Value and Risk in Health 2013). These two studies do not include the actuarial analysis of lung cancer screening by Pyenson et al. (Pyenson, Sander, Jiang, Kahn & Mulshine 2012). The registry categorizes and organizes studies according to their source, type of study, and other variables concerning how the study was performed. Studies are ranked in terms of quality from 1 (lowest) to 7 (highest), and a link is provided to the journal article for those who wish to view the original study. We consider this source useful for those with an academic orientation toward cost-effectiveness research, but generally not for the majority of actuaries.

Guidelines used for governmental payers include the health technology assessments that the National Institute for Health and Care Excellence (NICE) uses to evaluate studies for the National Health Service in the U.K., i.e., the single government payer. These assessments, which may also be published in the peer-reviewed literature, are performed according to guidelines generated and standardized by the government in the U.K., for use in its own national health service—a government-run, all-payer system of health care. Thus, manufacturers provide to the governmental body such evidence as is requested, in order to have their technology approved for use in the health plan for the entire country. The existence and publication of these assessments may help actuaries in the United States to understand what is considered valuable by the governmental single-payer plan in the U.K. This information may or may not be relevant to those working for U.S. health plans. Those who wish to learn more can utilize one of the many guides to Health Technology Assessment, such as "HTA 101: Introduction to Health Technology Assessment," available from the National Library of Medicine (Goodman 2004).

D. Audience for Evidence

One issue that is widely recognized by the HEOR community is that the evaluation of new medical technologies consists of two distinct elements. One element is the generation of evidence,

mainly through research, in order to determine efficacy—the product's performance in a well-controlled clinical trial setting, and effectiveness—the product's performance in the "real world," meaning its use in practice of new or existing products (Jackson 1995). The main rationale for research is to generate the evidence on health outcomes, costs, and other important aspects of the technology in order to show that it belongs in the armamentarium of medicine.

The second element of the evaluation of medical technology is in the communication of evidence. The communication of evidence is a key aspect of the evaluation of new medical technology, as important as the research used to generate evidence (Jackson 2009). There are multiple important stakeholders in health care, meaning different audiences, each of which requires a different style of communication to suit its needs. Researchers require detailed communication about the methodologies used to evaluate technology and study findings. Manufacturers require evidence in order to understand how their product fits in with the larger competitive marketplace of products that address a particular health condition. Providers require evidence that compares the effectiveness of different treatment options. Payers need information on comparative effectiveness and cost. Policymakers require evidence for multiple purposes—they provide funding to researchers, regulate the safety of products, ensure competition in the marketplace for health care, and oversee social insurance programs that provide health care benefits, such as Medicare and Medicaid. The evidence needs of each stakeholder are reflected, to an extent, in the types of communication that each community uses. Thus, it is well recognized that the communication of studies should be tailored to suit the needs of different stakeholders. Actuaries, as an audience, may be interested in these questions of value. It is important to note that cost alone is generally not the focus of HEOR evidence.

IV. Structured Tool

A. Purpose

In order to facilitate actuarial awareness of the evidence for value in health care, we created a new tool distinct from those created by ISPOR, AMCP, and other organizations. Our tool differs in that it is designed to organize HEOR evidence targeted to the needs of actuaries as we identified through this project. It answers our motivation by placing more emphasis on value rather than simply on cost, by giving actuaries a way to conceptualize the evidence needed to make decisions about technology adoption. As we have noted, other such tools are available for other stakeholders (see Section III). In this

way, the tool focuses on facilitating enhanced communication about evidence between actuaries and developers of medical technologies, with the purpose of giving a broad view of HEOR evidence, placed alongside actuarial evidence about medical technologies.

B. Structure of the Tool

The tool structures the information about a medical technology that we found most relevant into four main sections. The sections are designed to be cumulative, starting with broad questions and then building to sections with more specific questions. HEOR starts with the clinical and scientific basis for a disease state or indication, then focuses on a specific technology as appropriate for that disease state, compares the existing technologies, and arrives at a conclusion about the value of a specific technology both in absolute terms and relative to comparators. Similarly, our tool was designed to answer four questions in sequence:

1. What is the indication and/or disease state for the technology; i.e., why use this technology? What is the principal target and desired outcome(s) for the use of this technology?

2. What is the evidence for the technology; i.e., how well does it work? What is the evidence for performance under ideal circumstances, and what other sources of evidence are available?

3. How does the evidence apply to particular populations; i.e., how well does it work within a specific health plan? How well does it work relative to other active treatments, i.e., the real world standard?

4. How can the performance of a technology be assessed; i.e., how can we tell it is working for a given population with a specific health plan? How can the analysis of outcomes data be performed within a health plan?

We detail the way in which each question is addressed by the tool through a question-by-question list of instructions, available in the Appendix (Section VIII). The full, blank tool is available on the Health Research section of the SOA website (*www.soa.org*).

V. Conclusions

A. Using a Structured Tool in Practice

Use of the structured tool we have designed could take one of several forms. The principal use of our tool is to allow actuaries to summarize their understanding of a new technology, the evidence supporting its use, and how it will work in their plan. Since their perspective may focus on the financial aspects of plan management, they can become more informed by soliciting expert opinion regarding elements of the tool that require knowledge of HEOR. For example, those who work for a health plan can access their plan's P&T committee, medical director, or pharmacy director to ask questions about the strength of evidence for a technology adoption decision. The evaluation of medical technologies by actuaries could be prospective, in the sense of assessing technologies before they are approved by a plan, or retrospective, in the sense of assessing approved technologies, and reviewing their value. In either case, the tool gathers aspects of medical technologies that actuaries may find to be most pertinent in a single place.

A second use we envision for the tool is to understand the comparative effective evidence for a number of therapies for a specific condition or indication. An actuary could complete the tool for all relevant technologies within a particular therapeutic area and indication in partnership with clinical experts. Comparing differences between the tools filled out for each comparator could then be part of the decision about the adoption of new technologies as they become available. It could also be used to inform pricing and plan design, in order to build higher-value insurance plans. Finally, such a comparative exercise, performed by actuaries as part of a collaborative team, could facilitate the process of periodically reassessing all of the treatments for a given disease or indication (comparators) in order to understand the value of the treatments for which a health plan currently pays.

B. Implications for Actuarial Practice

Implementing this tool in practice could vary widely based on the needs of the actuary utilizing the tool. All health plans have existing methods that they use to decide on whether to introduce new medical technologies, and how to introduce them into a plan. Health plans also have existing methods for reviewing coverage decisions. For any plan, the tool can facilitate additional actuarial involvement in the decision-making process by introducing HEOR concepts and enhancing actuarial understanding of the evidence base. The tool could then be used to collect evidence in a structured way, as well as to

refine requests for additional evidence. This tool could also be useful to those actuaries whose main role is to assess the evidence base regarding new technologies, in order to facilitate the communications of findings to other actuaries.

In addition, this work could be used to improve health insurance more broadly by ensuring the implementation and use of high-value products and services by health plans. The value of any medical technology is based on its outcomes and its cost. HEOR already performs this research, and actuaries may be empowered to take it the "last mile" to adoption of medical technologies within a health plan. For example, a health plan in an area where providers are expected to rapidly adopt new therapies may see a different usage pattern when compared to an area where providers are more conservative in adoption of new technologies. As this type of plan-specific evidence is generally unavailable to researchers or suppliers, actuaries can play a valuable role by providing additional calls for evidence motivated by their own experience, as well as by providing valuable evidence on their own plan's real-world experience. All of these potential contributions to the evaluation of medical technologies can be facilitated by our tool, which synthesizes a range of evidence across an array of plan types.

C. Potential for Future Work

We envision future work to include refining the tool, validating the tool, and increasing the interaction between actuarial practice and the evaluators of medical technologies. It is our expectation that individual actuaries and others who use the tool will find changes or alterations necessary in order to allow it to suit their particular needs. In addition, with input from a sufficiently large user base, or the input and assessment of an expert panel, validation of the tool could be explored. Finally, it is our contention that actuaries and individuals in HEOR have a great deal to learn from one other, so it is our hope that this work will foster a dialogue, potentially leading to additional research or educational resources. We would be pleased to be a part of that effort.

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VII. Glossary and Abbreviations

Academy of Managed Care Pharmacy (AMCP)—"The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists, health care practitioners and others who develop and provide clinical, educational and business management services on behalf of more than 200 million Americans covered by a managed pharmacy benefit" (Academy of Managed Care Pharmacy 2013a). The organization consists mainly of pharmacists and other health care practitioners working in managed care settings.

AMCP dossier—An "... industry standard by which managed care organizations request information to evaluate new and existing pharmaceuticals for formulary placement, coverage and reimbursement decisions" (Academy of Managed Care Pharmacy 2013b). Dossiers consist of information on clinical and economic value of products, including the health outcomes, cost and cost-effectiveness of pharmaceuticals (Academy of Managed Care Pharmacy 2012; Academy of Managed Care Pharmacy 2013b).

Comparators—The set of all possible medical technologies that are appropriate for the prevention, diagnosis or treatment of a specific disease state and/or indication (Stürmer & Brookhart 2013).

Cost-effectiveness analysis (CEA)—A method for comparing the costs and benefits of different treatment options for a particular condition. Cost-effectiveness can also be used to compare the costs and benefits of different treatment options across conditions, although this use is more controversial (Edejer 2003).

Dominant treatment—A treatment that is more effective and less costly than the alternative for a given disease or indication. For an indication or disease where no treatment currently exists, a new medical technology that produces the same outcomes at a lower cost can also be considered a dominant treatment (Garber et al. 1996).

Effectiveness—"Whether a drug or other treatment works in real life. Effectiveness studies of drugs look at whether they work when they are used the way that most people take them. Effectiveness means that most people who have the disease would improve if they used the treatment" (Jackson 1995). Effectiveness can be contrasted with efficacy, which measures the outcomes of a treatment in a clinical trial.

Efficacy—In an efficacy study, participants are carefully selected and the researchers have control over various aspects of the study. Efficacy is a measure of **"**… whether a drug or other treatment works under the best possible conditions." In contrast to the real-world perspective of effectiveness, "… a treatment that has efficacy under the best conditions may not work as well in a different group of people with the same disease" (Agency for Healthcare Research and Quality 2013).

Evidence base—The body of evidence supporting the use of a particular medical technology in clinical practice, consisting of scientific research and other valid and reliable sources of data.

Health economics and outcomes research (HEOR)—A branch of health economics that is concerned with the assessment of new medical technologies. The main purposes of HEOR are to determine the relative value of new medical technologies, to allow individual health care decision makers to decide whether the value is adequate to recommend reimbursement, and to allow society to maximize the use of scarce health care resources by prioritizing those treatments with the highest value (Sloan & Conover 1995).

Health technology assessment (HTA)— "Any process of examining and reporting properties of a medical technology used in health care, such as safety, effectiveness, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended" (Shi & Singh 2011).

Incremental cost-effectiveness ratio (ICER)—A measure of the relative value of different treatments. The ratio expresses value in terms of the additional (incremental) cost of a more expensive therapy, divided by its additional (incremental) effectiveness, meaning improved health care outcomes (Folland, Goodman & Stano 2010).

Indication—The rationale for the use of a medical technology or "... the basis for initiation of a treatment for a disease or of a diagnostic test" (*Stedman's Medical Dictionary* 2006).

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)—ISPOR is a professional society of individuals engaged in the application and improvement of HEOR research. It is an organization that "promotes worldwide the science of pharmacoeconomics (health economics) and outcomes research (the scientific discipline that evaluates the effect of health care interventions on patient well-being including clinical, economic, and patient-centered outcomes) and facilitates the translation of this research into useful information for health care decision makers to increase the

efficiency, effectiveness, and fairness of health care to improve health" (International Society for Pharmacoeconomics and Outcomes Research 2013).

Medical technology—A collection of health care inputs designed to achieve an output of improved health. "… The application of science to develop solutions to health problems or issues such as the prevention or delay of onset of diseases or the promotion and monitoring of good health. Examples of medical technologies include medical and surgical procedures (angioplasty, joint replacements, organ transplants), diagnostic tests (laboratory tests, biopsies, imaging), drugs (biologic agents, pharmaceuticals, vaccines), medical devices (implantable defibrillators, stents), prosthetics (artificial body parts), and new support systems (electronic medical records, e-prescribing, and telemedicine)" (National Center for Health Statistics (U.S.) 2010).

National Health Service (NHS)—The health care system used in the United Kingdom. The National Health Service is primarily funded through central taxation, with the government managing the infrastructure for the delivery of health care, by owning hospitals, employing providers, and providing health care services directly to individuals (Shi & Singh 2011).

National Institute for Health and Care Excellence (NICE)—A public entity of the Department of Health in the United Kingdom that provides guidance and advice to improve health and social care (NICE: National Center for Health and Care Excellence 2013). NICE is the entity that evaluates medical technologies for the governmental National Health Service in the United Kingdom.

Patient-reported outcome (PRO)—A health outcome that is measured based on "… health data that is provided by the patient through a system of reporting. … Examples include physical abilities, fatigue, pain, depression, sexual function, and satisfaction with social participation (or interactions)" (PROMIS 2013).

Per member per month (PMPM)—The average cost of a treatment, disease, or patient population over a one-month time period. PMPM is calculated as the number of encounters per year (volume) multiplied by the average cost per encounter (price), divided by 12 (Cleverley et al. 2010).

Pharmacoeconomics—"… The description and analysis of the cost of drug therapy to healthcare systems and society." Additionally, pharmacoeconomics is the "process of identifying, measuring, and comparing the costs, risks, and benefits of programs, services, or therapies and determining which alternative produces the best health outcome for the resource invested" (Trask 2011).

Pharmacy and therapeutics (P&T) committee—A group of professionals in charge of managing the formulary system (list of drugs) in an institution (hospital, health plan, etc.). Members of the committee include physicians, other prescribers, pharmacists, nurses, administrators, and other health care professionals (Tyler et al. 2008).

Proxy measure—An indirect assessment of the effect of a treatment on the health of a patient. "Using a proxy measure means when you can't measure exactly what you want/need, you measure what you can. … Proxy measures are used when you can't exactly measure what you want or need (and) measure something that is close enough to reflect similarly" (Department of Family and Community Medicine, Duke University Medical Center 2005).

Table 1: Abbreviations used in this report

Abbreviation	Meaning
AMCP	Academy of Managed Care Pharmacy
CEA	Cost-effectiveness analysis
FDA	Food and Drug Administration
HEOR	Health economics and outcomes research
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PMPM	Per member per month
P&T	Pharmacy and therapeutics

VIII. Appendix—Instructions by Question

1. Classifying the Technology

The scope of classification of a medical technology describes the basic features of the technology. This includes basic information about the technology, as well as specific terms associated with the health plan's approval of the technology, guided by existing coverage benefits available at the health plan. Some information is health plan specific. For example, some health plans cover medical and drug benefits, while others cover only medical or only drug benefits. Thus, a medical procedure may have no specific "value" for a plan covering only drugs. The significance of the questions in the first section is to collect essential background information.

1.1. Enter the name of the medical technology, such as a drug, device, test, procedure, here.

1.2. Enter the name of the specific disease state or indication you are using to evaluate the technology with this tool.

1.3. Choose a restriction on utilization for the technology in your health plan from the drop-down menu. Restrictions could include *step therapy*, *prior authorization*, or *quantity limits* that are used to limit the utilization of drugs when placed on a health plan formulary. For treatments that are not drugs, similar restrictions may apply, as well as other restrictions such as review and approval by a plan medical director.

1.4. Choose the primary purpose that the technology was approved for in your health plan from the drop-down menu, whether for treatment of a disease, prevention of disease, or diagnosis of a disease. For example, hospital procedures for a patient suffering a heart attack would be considered a *treatment*, medication taken to prevent future heart attacks would be considered *prevention*, and laboratory tests used to determine the severity of heart disease that might cause a future heart attack would be considered *diagnosis*.

1.5. For each type of benefit, indicate whether your plan covers a technology in that benefit type, or does not cover a benefit in that type, by checking the appropriate box. For example, a cholesterol test would be considered as part of the *diagnostic—laboratory* category. If your plan covers this benefit, check the *covered by plan* box for this category. Otherwise, check the *not covered* box. As another example, atrial fibrillation would not be treated through substance

abuse intervention, so if the indication you are considering for a drug is atrial fibrillation, you would check the *does not exist* box under the *behavioral intervention—substance abuse* category. The "may not exist" category may be particularly challenging due to the wide array of treatments available for many conditions.

2. Evidence Base

This section assesses the evidence based on the research available to a health plan to determine the clinical and economic value of the technology. All covered medical technologies are supported by evidence that allows health plans to assess the value associated with covering a certain technology. However, the quality of this evidence will vary depending on the type of technology, when it was developed, and the indication. For example, when a manufacturer introduces a new drug, it also develops evidence about the outcomes and value of the new drug, and makes this evidence available to health plans at their request (FMCP Format Executive Committee 2010).

The body of evidence to support the value proposition of the technology is generated using a number of research methodologies. For example, "retrospective observational studies, prospective observational studies, randomized trials, ... economic analysis, surveys, and ... meta-analysis" (Krumholz 2009) are six examples of the methodologies used to evaluate medical technologies. Evidence is also assessed and validated by a range of organizations, including medical professional societies like the American College of Obstetrics and Gynecology (ACOG), and governmental bodies such as the FDA for drugs and devices. Evidence associated with health outcomes provides essential insight to determine how the technology works in a research setting and the "real world" implication of the technology. Evidence may be available related to specific health outcomes, or related only to proxy measures, which may weaken the appraisal of the technology. Additionally, cost data collected from a variety of heterogeneous data sources is of interest.

2.1. Enter the proven health outcomes and side effects of the technology for its specific indication by checking the appropriate box(es). Each type of outcome is distinct. For example, some treatments have been proven to increase survival, while others have proven reduced frequency of health-related events, such as heart attacks avoided without a proven link to lower mortality. Other treatments have proven patient-reported outcomes, like reduced pain. Finally, many treatments are proven to improve proxy measures of health, like reduced cholesterol or lower blood pressure. Side effects are possible in each of these categories. Some treatments

increase mortality, while others cause unwanted health-related events, such as excessive bleeding. Side effects for patient-reported outcomes can include increased depression or fatigue, while proxy measures of health could also be adversely affected, such as increased cholesterol and blood pressure.

2.2. Indicate the evidence type(s) by checking the appropriate box(es). Evidence on outcomes can take a number of forms, from randomized controlled trials performed in a controlled clinical setting to the retrospective analysis of claims data related to a particular disease. All papers or reports regarding evidence should state the type of evidence in the "methodology" or similar section of the document.

2.3. Indicate the type(s) of validation by checking the appropriate box(es). Some outcomes evidence can be externally validated, meaning that it has been reviewed or vetted by a third party. Published studies are externally validated, meaning they must be vetted by experts not involved in the study in order to be published. Other sources noted in the tool are alternative ways to assess the validity of a study.

2.4. Indicate the evidence type(s) by checking the appropriate box(es). Evidence on cost can come from similar sources as those noted in question 2.2. All papers or reports regarding evidence should state the type of evidence in the "methodology" or similar section of the document.

2.5. Indicate the type(s) of validation by checking the appropriate box(es). Some cost evidence can be externally validated, similar to the validation assessed in question 2.3. Each source noted in the tool is a way to assess the validity of cost data.

2.6. Indicate the evidence type(s) by checking the appropriate box(es). Evidence on cost-effectiveness can come from similar sources as those noted in questions 2.2 and 2.4. All papers or reports regarding evidence should state the type of evidence in the "methodology" or similar section of the document.

2.7. Indicate the type(s) of validation by checking the appropriate box(es). Some cost-effectiveness evidence can be externally validated, similar to the validation assessed in question 2.3. Each source noted in the tool is a way to assess the validity of cost-effectiveness data.

2.8. Answer this question using a free response (text). In the case where the tool is applied to an existing or previously approved technology, this question asks for an assessment of the

utilization of the technology in a health plan, which will often mean volume of care or total expenditure. This question should be answered based on internal data. In the case where a new technology is considered, it may be possible to model and/or predict the utilization rate if the technology were adopted.

2.9. Answer this question using a free response (text). In the case where the tool is applied to an existing or previously approved technology, this question asks for an assessment of the cost of the technology in a health plan, which will often mean pricing. This question should be answered based on internal data. In the case where a new technology is considered, it may be possible to model and/or predict the cost if the technology were adopted.

2.10. Answer this question using a free response (text). In the case where the tool is applied to an existing or previously approved technology, this question asks for an assessment of the outcomes of the technology in your health plan. This can take the form of improved health or reduced costs that may be assessed using internal claims or clinical data, depending on whether such data is available. In the case where a new technology is considered, it may be possible to model and/or predict the outcomes for the covered beneficiaries if the technology were adopted.

2.11. Indicate the answer as “Yes” or “No” by selecting from the drop-down box. The adoption of any new technology should include an assessment of all competing technologies (comparators). In the case of evaluating a new technology, a health plan would be concerned with comparing longstanding technologies with the new technology in order to make the most appropriate choice for the health plan and its members. In the case of reviewing available treatments, all longstanding technologies should be compared. If all of these therapies were not considered, the answer to this question would be “No.”

2.12. Indicate your rating by checking a box on a scale from 1 to 7. In reviewing the evidence summarized in this tool regarding the evidence for the use of a technology, this question should be answered based on the assessor’s sense of the methodologies used in the studies provided. For example, if no randomized controlled trials of a drug were performed, the methodological quality of the evidence could be considered low, and the drug would likely not be approved by the FDA in this case.

2.13. Indicate your rating by checking a box on a scale from 1 to 7. In reviewing the evidence summarized in this tool regarding the evidence for the use of a technology, this question should be answered based on the assessor's sense of the sample sizes used in the studies provided. For example, drugs are often evaluated using randomized controlled trials, while "… few new device evaluations (use) randomized controlled trials (RCTs)." (Sweet, Schwemm & Parsons 2011)

2.14. Indicate your rating by checking a box on a scale from 1 to 7. Health outcomes should be assessed based on their usefulness in supporting the adoption of a technology. For example, a study demonstrating improved survival will generally be considered as providing superior evidence of efficacy compared to a study demonstrating a reduction in heart attacks but not demonstrating improved survival. Determining the value of the types of outcomes, including patient reported outcomes and proxy measures, is a judgment call of the individual or group utilizing the tool.

2.15. Indicate your rating by checking a box on a scale from 1 to 7. This question is a summary of questions 2.12 through 2.14. It should summarize the entirety of the evidence base question in a single "score" indicating whether the research supports adoption of a technology.

2.16. Answer this question using a free response (text). This question allows for the inclusion of additional studies the assessor would like to see regarding a technology. For example, if a drug was approved for the general population, but limited evidence is available as to its effectiveness in certain groups of patients, such as those with multiple chronic conditions, that information should be provided in answer to this question.

3. Applying the Evidence

The perspective from which an actuary views a medical technology is based on utilization or potential utilization. Ultimately, the goal of a health plan could be to deliver valuable technologies to the end user—the patient. This section assesses the population in which this technology may be used within the health plan. The reason for the use of this section of the tool is to recognize that different health plans will cover different populations, and thus may have a different perspective regarding the value of a medical technology. Section 3 is concerned with the specific perspective of the health plan, in contrast

to the prior section, which is concerned with evidence that is generalizable to all evaluators of a medical technology.

3.1. Indicate the stakeholder(s) by checking the appropriate box(es). A technology can have implications for multiple stakeholders in a health care system. For example, employers may focus on employee productivity; the government may be concerned with the cost of social insurance programs, like Medicare; while the societal perspective would focus on a wide range of benefits, including the intrinsic value of a healthier population. Insurers may benefit from reduced costs or healthier plan members, while individuals benefit in a number of ways from better health. All stakeholders may be concerned with their costs for different technologies. Generally, multiple stakeholders will be affected, so multiple boxes can be checked.

3.2. Indicate the contribution(s) by checking the appropriate box(es). Each of the stakeholders noted in question 3.1 will have different goals, such as cost savings, improved health, and so on. There may be multiple effects of a technology, in which case multiple boxes can be checked.

3.3. Indicate the adverse effects(s) by checking the appropriate box(es). Each of the stakeholders noted in question 3.1 will want to avoid certain consequences of medical technologies, such as higher costs and negative side effects. There may be multiple outcomes of a technology, in which case multiple boxes can be checked.

3.4. Indicate your perspective(s) by checking the appropriate box(es). The tool was designed for multiple actuarial perspectives. Some actuaries may work in health plans sold on the nongroup or small group markets, while others may work on plans administered by the insurer on behalf of a self-funded employer plan. While the tool envisions one perspective for each use of the tool, there may be multiple perspectives by an individual or group using the tool.

3.5. Indicate the population(s) covered by the health plan by checking the appropriate box(es). This question applies variables that are used to describe the population covered by a health plan, such as age and gender, to the possibility that a medical technology has an indication specifically for certain populations. Age ranges coincide with plan types—for example, those only for children such as SCHIP; those for adults aged 65 and older with Medicare; and those that cover a range of age groups such as commercial (private) insurance.

3.6. Select a percentage of the population that is covered from the drop-down menu. The importance of a technology to a health plan will vary based on the number of members that might use the technology. This question elicits a range of the proportion of the plan expected to use a technology.

3.7. Indicate the type(s) of cost(s) by checking the appropriate box(es). Different technologies incur different types of costs. A surgical procedure could have a one-time cost, while a drug that is used long term, such as those designed to address chronic conditions like high cholesterol, may be used on an ongoing basis. There may be a mix of these costs, such as the one-time cost of a joint replacement surgery combined with ongoing costs of monitoring and rehabilitation from the surgery.

3.8. Answer this question using a free response (text). Cost estimates for a technology should be available based on actuarial estimates. A manufacturer may also provide a cost estimate, such as an interactive tool that combines data on the health plan with pricing data to derive an estimated PMPM cost for a new drug. This open response question elicits these and other estimates of the cost of a technology in a specific health plan.

3.9. Indicate the type(s) of spillover effect(s) by checking the appropriate box(es). Many technologies utilized for a specific disease affect other aspects of a patient's health or their health plan utilization. The side effects of any technology could cause additional costs for a plan, and/or offset costs such as by reducing the rate of hospitalization in a population. These types of spillovers could include other potential consequences of adopting a technology, such as attracting new types of members, attracting more costly members (adverse selection) or reducing the financial incentive for existing members to engage in preventative activities (moral hazard). Thus, multiple boxes can be checked.

3.10. Indicate the action(s) needed to add a medical technology to a plan by checking the appropriate box(es). Many technologies can be adopted by straightforward means, such as a drug added to a formulary or a new inpatient procedure in a plan that covers inpatient hospitalization. Other benefits may require a change in benefit design or a new type of benefit, or may even involve adding new patient populations to an existing plan.

4. Feedback Loop to Assess Performance

This section facilitates the development of a plan to assess the ongoing progress of the technology within the health plan once a technology has been implemented. The open-ended questions include the development of a timeline and the essential metrics necessary for a technology performance review or look-back analysis. Consequently, the results generated from such a review enable actuaries to communicate recommendations regarding continual coverage of the technology upfront. For a new technology, this section allows actuaries to facilitate the process of plan monitoring, establishing expected results from a new product, and then comparing expected results to actual data. For an existing technology, this section allows actuaries to determine what type of data they already have about the use of a specific technology, allowing them to plan analyses or other reviews of how well the technology is working.

4.1. Answer this question using a free response (text). Actuaries may be able to pre-specify the types of outcomes data they will receive, and the sources of that data. To the extent that is possible, this question assesses the broad strategies for assessing outcomes within a health plan.

4.2. Answer this question using a free response (text). Actuaries may want to determine ahead of time how they will assess the data on newly adopted technologies. This question elicits planning for the process of collecting and assessing specific data in a forward-looking fashion.

4.3. Answer this question using a free response (text). This question assesses the incurring and assessment of claims. This process is geared both toward the collection of data, assessed in question 4.2, and to any process for reviewing claims, such as prior authorization procedures or utilization reviews.