Private Health Insurance Coverage and Payment Policies and Decisionmaking Processes for Genetic Technologies and Services
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DR. MCCABE: I think, as all of you will recall, the committee really decided that this was an important issue, coverage and reimbursement, at our October meeting, and will help add background to our priority-setting deliberations, which will continue tomorrow morning. I want to thank all of the presenters for taking time from your busy lives to be here with us. We look forward to an enlightening series of talks that are going to come at this from a variety of different perspectives.

Because of the time constraints, I'm not going to go through extensive bios. Those are under Tab 1 in your briefing books, and copies of the presenters' PowerPoint slides are in the table folders, this white folder that was at your position this morning.

So our first presentation of the afternoon is by Dr. Michele Schoonmaker, who will brief us about coverage and payment decisions and how they're made for genetic technologies and services by private health plans. Dr. Schoonmaker is on the staff of the Congressional Research Service of the Library of Congress. This group provides objective, bipartisan analyses to Congress on genetics issues.

Dr. Schoonmaker?

DR. SCHOONMAKER: Good afternoon, Mr. Chairman, members of the committee, and the public. Thank you for inviting me to participate in this session on the coverage of genetic tests and services. The views I will present are my own and do not reflect the views of the Congressional Research Service or the Library of Congress.

I'll begin by briefly describing health insurance coverage in the U.S., and I'll focus mainly on how private insurers make decisions to cover new genetic tests. Then we'll provide a general overview for how they pay for them. Throughout, I will give examples of existing coverage policies for genetic technologies.

In 2002, almost 44 million people were uninsured. Seventy-two million were covered by a public program, such as Medicare or Medicaid or the military, while the majority, or 199 million people, had private insurance. Of those with private insurance, 88 percent were covered by group policies, usually through their employers, and 12 percent purchased individual policies. The percents don't add up to 100 percent because there are about 29 million people who were counted in more than one group during the year, for example that moved between being uninsured and being on Medicaid.

There are two main types of private insurance products. In indemnity insurance, the insurer provides financing only. The insurer pays a provider a fee for service after the patient has received the service. Because indemnity insurance originated to protect people from the high cost of injury or illness, historically benefits excluded preventive services. Most of today's indemnity plans have adopted some element of managed care.

Managed care emerged in the 1980s as an incentive to reduce the cost of health care. Managed care insurers do this by coordinating the financing of care with the delivery of services. Prior authorization and case management are two of the tools used to encourage patients to see certain

providers or to control their access to certain types of services. For prior authorization, a patient has to get payer approval before seeking care. In case management, a provider coordinates care through referrals. These practices aim at ensuring that a patient receives only medically necessary services. Unlike indemnity insurance, most managed care products generally include some coverage for preventive services.

Managed care products span a continuum of possible arrangements. Health maintenance organizations are the most managed in that they completely integrate the financing and delivery of services. Physicians are usually salaried employees or paid per member per month regardless of whether or not a patient actually seeks care. HMO patients must see HMO network providers or care generally won't be covered. In a provider organization, the payer contracts with networks of physicians for primary care specialty services. The provider and the payer negotiate discounted fees in exchange for a higher volume of referrals.

A point of service plan is a hybrid between the HMO and the PPO arrangement. The point of service evolved to give patients more freedom in their choice of provider. The patient can choose an in-network provider and have HMO-like benefits with low co-payments, or they can choose to go out of network but with higher co-payments.

I've included the last two slides because it's important to understand the distinction, because the type of organization can impact how coverage decisions are made and how the providers are reimbursed.

I'll now discuss how coverage policies are made and provide examples of existing policies. To prepare for the upcoming slides, I looked at the websites of 125 private health insurers. Though 44 of them posted their coverage policies, only 27 allowed unrestricted access. Of the 27, 24 had posted policies related to genetic tests or services. Sixteen of these were Blue Cross/Blue Shield plans, and eight were other companies.

Insurers make coverage decisions in two main ways. The insurance contract or a policy that an individual or employer can purchase can outline a broad benefit category, such as laboratory tests. Decisions about a specific test are then made on a case-by-case basis when the claims are processed. Alternatively, insurers can develop a coverage policy. The policy is a more precise description of the exact service that will be covered, and the conditions for which it will be covered. Policies are usually developed to respond to new technologies, to new information about a technology, or in response to mandates. Policies define what the insurer considers to be medically necessary, and they state limits on the types of providers that can perform the service or can limit the number of times a patient can receive a service. The coverage policy is written as a guideline. The exact benefits for an individual are usually still determined by what their insurance contract says.

For almost all private insurers, a medical director will decide the benefits, sometimes in conjunction with a medical policy advisory committee. The committees also often include other plan personnel, as well as local medical experts, consumers, or legal counsel. Employers can decide benefits. Regardless of what an insurance coverage policy says, the employers, usually the CEO or human resources director, can negotiate with the insurer for inclusion or exclusion of specific services. Other large groups, such as unions, churches, academic centers, can negotiate benefits on behalf of individuals; and, of course, federal and state governments can mandate coverage.

What criteria do plans use to determine what services to cover? Almost unanimously, decisions

are based on medical necessity. However, like beauty, medical necessity can be in the eye of the beholder. While most plans don't publish specific definitions, others have developed very explicit criteria. The following are the Blue Cross/Blue Shield Association's criteria for deciding coverage.

First, the technology must have final approval from the appropriate regulatory body. Once approved by the body, the TEC, or technology evaluation center, is not bound by the indications in the approval. They can evaluate off-label uses.

Second, the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The evidence is evaluated in terms of quality and consistency of results. The evidence should demonstrate that the technology can measure changes related to the disease, and that the measurements actually affect the outcomes. The technology must improve the outcome, and the benefit must be as big or bigger than established alternatives, and be attainable outside of an investigational setting.

So in order for Blue Cross/Blue Shield to recommend coverage for a new genetic test, the test must have FDA approval or conform to the CLIA requirements, evidence must show that the test measures what it's supposed to measure, and that the test will positively impact patient outcomes in the real world.

I want to point out that criteria 3 and 4 go beyond what is necessary for regulatory approval of a new test. Rarely would FDA require that an applicant measure actual clinical outcomes, let alone determine the magnitude of benefit in order to gain approval. CLIA regulates the process of testing but doesn't say much about the evaluation of the test itself. And although Blue Cross/Blue Shield doesn't explicitly use cost-effectiveness, one or two other insurers considered cost-effectiveness but they didn't describe how the criterion is applied.

So where do payers look for scientific evidence? Looking at the reference section of the existing coverage policies, payers primarily rely on the literature, statements from professional organizations, and government agencies. Many turn to the work of technology assessment groups, and some payers adopt all or part of the policies from other payers. Compared to work I did only three years ago, many more payers are turning to the websites as a primary source of information.

Looking at existing policies, private insurers generally find genetic testing medically necessary when personal or family history indicates a high risk for inherited conditions, when the sensitivity of a test is known, when the results will directly impact the treatment or management of the patient, when the diagnosis remains uncertain following conventional workup, and interestingly, where pre- and post-test counseling is provided as appropriate. A few policies even went so far as to specify what the informed consent should be.

In general, genetic testing was not covered for population screening without a personal or family history, regardless of ethnicity. The only notable exception was coverage for CF carrier screening as a preconception service to what one policy called "informed couples," or as a prenatal service to pregnant women. Testing is not covered for informational purposes only or for testing minors for adult-onset diseases. Coverage is usually not provided for a patient's family member who is not also a member of the health plan unless the information from that family member, such as the identification of a specific mutation, is necessary to make an appropriate medical decision for the plan member, and the family's member can prove that they've already tried to get insurance coverage from their insurance company and they were denied.

Nearly all insurers cover tests for chromosomal abnormalities. Most are written for prenatal or neonatal diagnosis, but some insurers have also written policies for preimplantation diagnosis. Covered indications include advanced maternal age, suspected fetal anomaly, history of multiple miscarriage or developmental problems, et cetera. Tests for rare single-gene disorders are usually covered under general policies for genetic testing and counseling. However, some insurers have separate policies for specific conditions, and some of those are for hereditary cancer testing, cystic fibrosis, Tay-Sachs, or hemochromatosis.

Policies for pharmacogenetic or pharmacogenomic tests can be written either in the context of the drug policy, such as for Herceptin, or they can be written separately, one policy for the drug, another policy for the test. Some drug policies simply list the prescribing characteristics, such as HER-2-positive, without saying how the characteristic is to be determined.

I'm going to give you a few examples of policies that have been written. You might be surprised to find out that 12 insurers have written a policy for testing for the genetic markers associated with familial Alzheimer's disease, but none of the policies cover the test. Using primarily the Blue Cross/Blue Shield criteria, these insurers concluded that testing is investigational. There is insufficient information to demonstrate that the genotypes are associated with Alzheimer's disease with a high positive predictive value.

The second example concerns colon cancer testing. There are two kinds of hereditary colon cancer. Hereditary non-polyposis colon cancer is typically diagnosed based on family history and is associated with mutations in two main genes, the MLH1 and MSH2. Familial adenomatosis polyposis, or FAP, is based on personal signs such as the presence of at least 20 polyps in the colon. The patient usually has at least one first-degree relative with the disease. FAP is associated with mutations in the APC gene.

Sixteen insurers have developed policies for genetic testing. Four cover testing without specifying the genes. Five cover mutation analysis in three common genes, four cover microsatellite instability analysis in addition to the common gene tests, one covered APC testing only, and two did not cover genetic testing but would cover other means of diagnosis. Common exclusions in the policies were microsatellite instability analysis in the stool specimen, and specifically testing for the I1307K mutation in the APC gene.

The point with this example is that even though 14 out of the 16 insurers that had policies covered the genetic testing, they varied in the level of detail and also in the specific analyses that they covered.

To give you a pharmacogenomic example, azathioprine is an immunosuppressant treatment for inflammatory bowel disease. It is converted into active metabolites by an enzyme called TPMT. The activity of TPMT is associated with genotype. Ninety percent of patients are homozygous for wild-type form of the enzyme and have high TPMT activity. Ten percent are heterozygous for a mutation that reduces enzyme activity, and overall they have an intermediate activity. Finally, a small percentage are homozygous for the mutant phenotype, and these patients have extremely low enzyme activity and are at risk for toxicity.

People who are homozygous wild type could receive a standard dose of the drug, and although no studies have measured the outcomes based on knowing the genotype beforehand, the thinking is that a provider would prescribe a different drug or monitor metabolite levels for those with the homozygous mutations, or reduce the dose for heterozygotes. Six insurers have written policies

for genotyping the TPMT gene. Three covered both genetic testing and monitoring of the metabolite markers. Two covered only the metabolite markers, and one did not cover either test.

Once an insurer decides to cover a new test or service, they have to determine how much they're going to pay for it. Payment rates are based on many factors, including where the services are provided and the usual and customary charges billed by the providers in that location. Reimbursement rates can be a simple percentage of bill charges that is determined in the insurance contract, insurers can negotiate fees with different providers, or adopt a fee schedule such as those used by Medicare, or they can come up with their own fee schedule. Just because a policy said that a test is covered doesn't mean that it will be paid at a rate the providers find adequate. The reality of the situation is that poor payment can have the same impact as a non-coverage decision.

The payment process involves recognition of a service by the insurer. This is done through the common coding systems. The ICD-9 code tells the payer why a service was done. It codes for the diagnosis, disease condition, signs or symptoms that the patient has. The CPT identifies the procedure or the service that was performed. Basically, if the CPT, or the service, matches the medically appropriate reason, or the ICD-9, then the claim can be paid. Of course, this depends on the provider submitting first the correct information, especially with regard to identifiers and dates of service, and second, where it's required, documentation. The documentation could be a pedigree to show family history, or literature to support the medical necessity of a new service.

The CPT codes used to identify genetic tests are limited. There are codes for molecular diagnostic procedures and for cytogenetics. Usually you have to string together multiple codes to describe a whole test. Providers often complain that these unbundled codes have lower payments associated with them than would a code for a whole test. There have been problems in the past as to what laboratory specialties can use which codes, particularly the molecular codes that are in the cytogenetic section.

Each coding section ends with a code that's three digits plus 99. The 99 codes are for unlisted or new procedures. These are often perceived by insurers to be investigational, indicating that we need timely development of new codes. As many in the audience know, getting a new code can take years. The HCPCS, or Health Care Common Procedure Coding System, is a national temporary coding system that can be established for new tests. Many have recently been developed for gene sequencing and mutation analysis for specific conditions. For example, you'd use an S3820 for a complete BRCA1/BRCA2 gene sequence analysis, and an S3822 for a single mutation analysis for an individual with a known BRCA1 or BRCA2 mutation in their family. Later, my colleagues will go into more detail about payment issues with laboratory tests and with professional services.

So with that, to sum up, testing for the most traditional inherited genetic conditions is covered by most private insurers, including counseling, but that doesn't mean that there's adequate reimbursement. There still seems to be the perception that insurers are slow in covering new technologies. Insurers may argue that this is because there isn't any data to support the medical benefit of the new test. This situation may in part be due to the fact that the studies designed to meet regulatory requirements rarely evaluate whether the information from the test will impact patient management, and if so, how. As far as payment is concerned, providers need to go through the cost analysis with insurers so that payers understand how costs are applied and where reimbursement rates are failing. Like many other things, at the heart of the issue is a need for balanced communication and education with respect to the risks, benefits, and responsible use of genetic technologies. With that, thank you.