Searching for significance

Plans and providers trudge through the labyrinth of genetic information in search for appropriate coverage and care

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The ruckus over designer babies, human cloning and genetic discrimination has colored much of the debate and perception of genetic services, but the discipline is gaining momentum as research propels new tests to determine the susceptibility to more common diseases, as well as a slew of rare ones.

Although the applicability of genomics largely has been confined to prenatal care and carrier screening for the past few decades, clinical specialists and health plans have begun to confront opportunities where genetic screening is appropriate for some adult-onset disorders.

"Most medically oriented sub-specialists, as opposed to surgical sub-specialists, will need to know about genetic testing because it's the rare disorders that they deal with routinely that are often genetic. Neurologists are a good example," says Roberta Pagon, MD, clinical geneticist, principal investigator for GeneTests-GeneClinics, the federally funded information initiative. "There are a huge number-180 or more-of neurological diseases for which clinical genetic testing is available. [Specialists] need to know how to use genetic testing if they are going to take appropriate care of the patients who come in with a whole host of different findings."

Though it's unlikely that non-geneticists will need to understand the science behind the human genome project, medical specialists increasingly will need to interpret tests and make referrals to genetic clinics for a growing number of disorders. Subsequently, many plans soon will need to make some tough decisions about which tests to cover. The current education process for plans is not very effective, Pagon says.

"Each provider that is trying to get a test covered for a patient has to educate the person on the other line about why it is appropriate; that's a big burden for physicians trying to use genetic testing for patient care," she says. "We need to get better information to third-party payers so that they know what they are buying. That issue is near and dear to the heart of any geneticist. Plans need to get educated at a policy level about what they are going to reimburse and why they are reimbursing for certain things and not others."

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Many plans have confronted the issue of predictive screening (testing for the presence of a genetic risk factor) for breast cancer with the testing for the presence of BRCA1 and BRCA2 genes, as well as for susceptibility to hereditary nonpolyposis colorectal cancer.

A 1998 survey, funded and published by the Robert Wood Johnson Foundation, showed that payers approved coverage for breast cancer testing 45% of the time and for colon cancer more than 40% of the time. Though the survey indicates that plans are warming to the benefits of pre-symptomatic diagnosis, more than 90% of the responding genetic-unit administrators reported difficulty providing services for patients enrolled in managed care organizations.

The expense of genetic tests and consultations likely have dissuaded plans a bit, but the complexity of genetic care and the sometimes complex processes associated with diagnosis has been a tough pill to swallow, too. It’s especially difficult when trying to diagnose an individual who might have a hereditary disease that requires the testing of multiple family members, who oftentimes are covered by different health plans, says Alan Bombard, clinical geneticist, senior vice president and chair of OB/GYN for Lutheran Medical Center in Brooklyn, N.Y. Bombard recently presented material to the Secretary’s Advisory Panel for Genetic Testing based on his five-year tenure at Aetna, where he crafted corporate coverage guidelines for the company; he left Aetna for his current position earlier this year.

"Aetna looks at who needs the testing in the family, and if the person that needs the testing is an Aetna member, then Aetna pays for it if the tests aren’t covered by other plans," Bombard says. "If an Aetna patient happens to be a member of a family and a test needs to be done for the benefit of someone else, then Aetna won’t pay for it.

"So you have to decide who will derive the medical benefit for that, and that makes the most sense. Most health plans provide services that are medically appropriate and a benefit to their members, and for which the information will result in a change in health management."

Aetna makes its policies available on the Web for the benefit of those inside and outside the network. The American College of Medical Genetics also has issued payer guidelines, which can help providers in determining appropriate genetic care.

"Once we had the guidelines in place, providers were making more appropriate referrals; we outlined for them what the standard of practice was. Ultimately, the guidelines helped clarify for the docs what the indications were for the testing: what is needed for the patient in terms of counseling—such as pedigree analysis, risk assessment—and how that test is going to change your healthcare. Then comes the documentation, but it begins as an educational process."

Medical geneticists and certified genetic consultants [see Visionaries, p. 24] could help plans navigate the wealth of genetic evidence in a consulting role as payers go through this process of devising payment guidelines. For cases that fall outside established standards, "genetic consultants can be very useful by contracting with them on a case-by-case basis or as a full-time professional, if volume dictates," says Jonathan Edwards, senior research analyst for GartnerG2, a division of The Gartner Group.

Managing the data that accompanies genetic care likely will be a challenge, but one many physicians are accustomed to, says Joann Boughman, executive vice president for the American Society of Human Genetics.

"Physicians already manage huge
Aetna suggests guides for access to genetic testing

HEALTH PLANS CAN play an important role in promoting access to clinically useful genetic testing and the proper interpretation of test results, according to Aetna CEO John W. Rowe, MD.

Rowe called on plans to make available products to their self-insured plan sponsors and their fully insured customers that cover genetic testing and consultation, support physician and patient education and work with physicians to promote strict confidentiality of test results.

"There is a pressing need for the health insurance industry to establish guidelines for covering genetic testing in a way that promotes disease prevention and disease management, while at the same time respecting members' privacy," he says.

Aetna believes genetic testing represents less than one-tenth of 1% of its medical spending last year. Aetna covers about 40 genetic tests including those for Huntington's disease, breast cancer, Tay-Sachs disease and cystic fibrosis.

— Tracey Walker

Clinical computing systems likely will fuel understanding and appropriate referrals; education portals such as GeneTests-GeneClinics also provide physician information about how to use and interpret genetic tests, among other resources for plans, providers and patients.

"The investment at this point should not be in technology; it should be in expertise," Pagon says. "The investment is going to come from the appropriate use of genetic counseling services. You need to have doctors who can determine if a patient is at risk for a genetic disorder. The next step is using genetics professionals; the cost of a referral to a genetic professional varies, but it is no different from seeing a cardiologist or hematologist, for example."

Pharmacogenomics

Though researchers are some years away from designing drugs tailored for each person's disease, some of the heavy investment that pharmaceutical companies are sinking into genetic research is starting to pay off.

Herceptin, a breast cancer therapy that failed clinical trials, has been remarkeeted with a genetic test that screens out those who show susceptibility to an adverse reaction. The discovery was an accident, Handler says, but it's prompting the pharmaceutical manufacturers to revisit shelved therapies in an attempt to recapture lost research and development investments.

"The scientists discovered that the people who had these side effects from Herceptin had a certain genetic variation that can be screened for. The individuals that did not have that genetic variation were able to take the drug, and it was 100% effective," Handler says. "So the pharma companies all are feverishly working other drugs that failed clinical trials; in the next few years we'll see a significant increase in genetic testing in conjunction with those therapies being brought back on the market."

The surge in information about, requests for, and specialty of genetic testing and diagnosis could give rise to more evidence for payers to base their drug-coverage decisions. Otherwise, new therapies likely will be missing from many formularies until enough evidence exists to justify the more expensive treatments.

"There is going to be a big push toward outcomes to measure return on investment on these drugs. All of that is going to push providers to implement more clinical computing infrastructure," Handler says. "They will have it in place when the time comes for these drugs to hit the market in five or 10 years."

In the meantime, "the real opportunity in genetics is true preventive diagnosis and preventive testing," Bombard says. "There's an up-front cost, but one has to look at recruiting patients into your health plan for the long term—focusing on customer service, giving patients what they want and what they need, and hoping that if you provide your patients with the best care, they will stay with you."