

►► **CEO SUMMARY: Pre-authorization of genetic tests is coming to physicians serving patients insured by Anthem, Inc. Its specialty benefits management company, AIM Specialty Health, will manage the program. AIM will work with InformedDNA, a company that specializes in genetic testing clinical decision support and genetic counseling for health insurers. Anthem has about 40 million members in 14 states.**

Nation's largest health insurer to require pre-authorization

Anthem Launches Program to Manage Genetic Tests

WHAT IS EXPECTED TO BE the nation's largest genetic testing management program will begin on July 1. In 14 states, **Anthem** will require in-network physicians serving its members to obtain pre-authorization for certain genetic tests.

Anthem's Genetic Testing Solution will require physicians to use an online portal or to call utilization management to get prior-authorization for genetic tests that fall under one of 45 of Anthem's genetic testing coverage criteria, as outlined on Anthem's Medical Policies and Clinical UM Guidelines site.

AIM Specialty Health, a specialty benefits management company that Anthem owns, will manage the program. For the program, AIM plans to work with **InformedDNA**, a company in St.

Petersburg, Fla., that specializes in genetic testing clinical decision support and genetic counseling for health insurers.

In 2013, **Cigna** announced that InformedDNA would provide independent genetic counseling for some gene tests for Cigna members. Last year, Cigna expanded that program. (See *TDRs*, Aug. 19, 2013 and Dec. 15, 2014.)

The fact that Anthem is launching a genetic test management program is significant because it is one of the nation's largest health insurers by enrollment. In its most recent quarterly report, Anthem said it has 40 million members in California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, and Wisconsin.

Nearly all health insurers struggle to meet the demand for genetic testing and to develop systems to manage requests for these tests. Last year, almost 70,000 genetic testing products were available, according to **Concert Genetics**, which tracks such tests.

Concert Genetics defines a testing product as an individual gene test or multiple gene panels. The nation's labs introduce more than 10 new genetic tests every day, Mark Harris, PhD, MBA, Founder and Chief Innovation Officer of Concert Genetics, reported at the *Executive War College* in May.

program this fall and three others will begin on Jan. 1, 2018, explained Lewis.

► Inappropriate Test Orders

When it announced the program in April, AIM cited research showing that 30% to 50% of genetic tests may be ordered inappropriately. Incorrect test orders push up costs unnecessarily and lead to poor patient care, AIM said.

In addition, AIM cited a market prediction from 2015, "Genetic Testing: A Global Strategic Business Report," by **Global Industry Analysts** that forecast that the

"Anthem recognizes that the appropriate use and interpretation of genetic testing is a priority, not just for all health plans but also for physicians and for patients," stated Karen Lewis, a genetic counselor with extensive experience working in clinical and genetic testing labs.

The Director of AIM's Genetic Testing Solution, Lewis said, "The vast majority of health plans—whether they are large or small—are looking either for outside help or they are doing their own internal reviews of genetic test requests. As they see the volume of requests rise, it was just a matter of time before health plans put some solution in place."

The AIM Genetic Testing Solution is available to other health plans. One health plan in the Northeast will begin using AIM's

global market for genetic tests would reach \$7.4 billion by 2020.

Physicians have no experience with AIM's genetic testing management program when seeking pre-authorization for genetic test orders, so Lewis could not say if physicians will find it easier than the current system Anthem uses. She did say, however, that Anthem's current system is labor intensive. However, when physicians in other specialties use AIM's provider portal system to order tests and procedures, surveys show those physicians have a 96% satisfaction rating for ease of use.

"For physicians ordering genetic tests, Anthem has 45 genetic testing medical policies," Lewis said. "That makes it difficult for them to wrap their arms around those policies efficiently. (See sidebar on page 13.)

“Our program is designed to work with those policies so that providers can easily identify the tests they need and get the authorization for those tests in a timely fashion,” she continued. “It’s all done electronically. So, depending on what genetic test a physician orders and the policies behind that test, the physician could have an authorization in less than a minute.”

A minute for prior authorization for a genetic test? That would seem to be much faster than the lab test pre-approval processes most health plans use today.

“To be honest,” Lewis responded. “Many requests for pre-approval of a genetic test will take more than a minute. Obviously, it depends on the test. Some genetic tests require complicated algorithms. And some tests involve a lot of questions and answers over a few minutes.

“But if it’s a cystic fibrosis carrier screening test, then that request takes a minute. A physician will be in and out of the system easily,” she noted.

► A Portal For Entry

“Most physicians working with Anthem will use the provider portal for pre-approval of genetic testing,” said Lewis. “Also, they can call in to request approval for a genetic test. Many of our providers prefer to use the AIM portal. It allows them to select the genetic test and select the lab. Then, if there are questions, they can answer them online and get an authorization.

“That’s a very efficient way for providers to access genetic testing and for our client-payers to adjudicate requests against their policies,” she commented.

“Like most payers, Anthem requires counseling for many genetic tests, and when counseling is required, we make sure that happens,” she said. “Many doctors who regularly order genetic tests may already have a network of genetic counselors, or they do the counseling themselves.

“Physicians who are uncomfortable with genetic testing or don’t have access to a network of genetic counselors can access a database of genetic counselors through AIM,” Lewis said. “Genetic counseling can be done by phone, via telehealth, or face to face.” One of the companies that provides genetic counselors is InformedDNA.

► Easier Than Current System

“Allowing physicians to use AIM’s provider portal to order genetic tests will be much easier than the current system Anthem’s in-network physicians use for test ordering,” Lewis explained. “Currently, the onus is on the provider to verify a genetic test order against medical policy and to verify whether a test meets Anthem’s medical necessity requirements. The physicians also must verify whatever lab they intend to use.

“After they do all that, then they submit the paperwork requisition to the lab, and the lab runs the test,” she explained. “The problem with this process is that it is a post-service review. In this scenario, if the lab runs the genetic test without an approval, there could be a denial of coverage, and no one is happy about that.

“The benefit of using AIM’s provider portal or calling on the phone is that the physician would get the pre-authorization *before* the lab runs the test,” emphasized Lewis. “At that stage, the physician knows that the lab is in-network and both the physician and the lab know the medical policy for the genetic test in question. And they know all of this information before they run the test.

“For this reason, we should see a tremendous decrease in post-service denials,” she added. “Post-service denials are a problem because once the genetic test is done, the lab wants to get paid and often they bill the patient. Patients don’t like that, obviously, and neither do physicians.

“The expectation is that most genetic tests that in-network physicians will order will go through in-network labs,” said

Anthem Lists 45 Genetic Test Policies

- GENE.00001 Genetic Testing for Cancer Susceptibility
- GENE.00002 Preimplantation Genetic Diagnosis Testing
- GENE.00003 Genetic Testing and Biochemical Markers for the Diagnosis of Alzheimer's Disease
- GENE.00004 Janus Kinase 2 (JAK2)V617F Gene Mutation Assay
- GENE.00005 BCR-ABL Mutation Analysis
- GENE.00006 Epidermal Growth Factor Receptor (EGFR) Testing
- GENE.00007 Cardiac Ion Channel Genetic Testing
- GENE.00008 Analysis of Fecal DNA for Colorectal Cancer Screening
- GENE.00009 Gene-Based Tests for Screening, Detection and Management of Prostate Cancer
- GENE.00010 Genotype Testing for Genetic Polymorphisms to Determine Drug-Metabolizer Status
- GENE.00011 Gene Expression Profiling for Managing Breast Cancer Treatment
- GENE.00012 Preconceptional or Prenatal Genetic Testing of a Parent or Prospective Parent
- GENE.00014 Analysis of KRAS Status
- GENE.00016 Gene Expression Profiling for Colorectal Cancer
- GENE.00017 Genetic Testing for Diagnosis and Management of Hereditary Cardiomyopathies (including ARVD/C)
- GENE.00018 Gene Expression Profiling for Cancers of Unknown Primary Site
- GENE.00019 BRAF Mutation Analysis
- GENE.00020 Gene Expression Profile Tests for Multiple Myeloma
- GENE.00021 Chromosomal Microarray Analysis (CMA) for Developmental Delay, Autism Spectrum Disorder, Intellectual Disability (Intellectual Developmental Disorder), and Congenital Anomalies.
- GENE.00022 In Vitro Companion Diagnostic Devices
- GENE.00023 Gene Expression Profiling of Melanomas
- GENE.00024 DNA-Based Testing for Adolescent Idiopathic Scoliosis
- GENE.00025 Molecular Profiling and Proteogenomic Testing for Evaluation of Malignant Tumors
- GENE.00026 Cell-Free Fetal DNA-Based Prenatal Testing
- GENE.00027 Combined PALB2 and BRCA2 Mutation Testing for Oncologic Indications
- GENE.00028 Genetic Testing for Colorectal Cancer Susceptibility
- GENE.00029 Genetic Testing for Breast and/or Ovarian Cancer Syndrome
- GENE.00030 Genetic Testing for Endocrine Gland Cancer Susceptibility
- GENE.00031 Genetic Testing for PTEN Hamartoma Tumor Syndrome
- GENE.00032 Molecular Marker Evaluation of Thyroid Nodules
- GENE.00033 Genetic Testing for Inherited Peripheral Neuropathies
- GENE.00034 SensiGene® Fetal RhD Genotyping Test
- GENE.00035 Genetic Testing for TP53 Mutations
- GENE.00036 Genetic Testing for Hereditary Pancreatitis
- GENE.00037 Genetic Testing for Macular Degeneration
- GENE.00038 Genetic Testing for Statin-Induced Myopathy
- GENE.00039 Genetic Testing for Frontotemporal Dementia (FTD)
- GENE.00040 Genetic Testing for CHARGE Syndrome
- GENE.00041 Short Tandem Repeat Analysis for Specimen Provenance Testing
- GENE.00042 Genetic Testing for Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) Syndrome
- GENE.00043 Genetic Testing of an Individual's Genome for Inherited Diseases
- GENE.00044 Analysis of PIK3CA Status in Tumor Cells
- GENE.00045 Detection and Quantification of Tumor DNA Using Next Generation Sequencing in Lymphoid Cancers
- GENE.00046 Prothrombin G20210A (Factor II) Mutation Testing
- GENE.00047 Methylene tetrahydrofolate Reductase Mutation Testing

Nation's Health Insurers Struggle To Meet Fast-Growing Demand for Genetic Tests

ALL THE PROBLEMS ASSOCIATED WITH GENETIC TESTING were obvious to Karen Lewis, who is the Director of Genetic Testing Solution for AIM Specialty Health, a division of Anthem. The need for a genetic test management program was obvious.

Health insurers were struggling to stay up with the demand for genetic tests. Physicians and patients were frustrated because too often requests sent to health insurers for approvals were denied or took too long. Labs that performed the genetic tests were unsure they would get paid.

These factors led Anthem to create AIM Specialty Health and its Genetic Test Solution. In her role, Lewis will oversee the launch of AIM and Anthem's national genetic testing management program that begins next month.

"Once Anthem started this program for its own physicians and beneficiaries, many other payers came to us asking for help," said Lewis. "They said requests for genetic tests were so far beyond the scope of their comfort level that they needed assistance from someone.

"From personal experience, I knew how insurers struggle to evaluate and approve these tests," she said. "Here in Michigan, I worked on an insurer's technology assessment policy committee. Its managers needed help writing medical policies governing the use of genetic tests as well as help in reviewing claims. They also needed help to understand the growing volume of genetic tests introduced every day.

"Even now, many payers are just barely getting by as they attempt to keep up with the demand for test approvals," she added. "They find it challenging. That's why they contacted AIM and asked us for help. This led us to create AIM's Genetic Testing Solution for one payer starting this fall. As of Jan. 1, multiple payers will begin to use the solution.

"Currently, Anthem is our largest customer, but we are adding other insurers as well," said Lewis, a board-certified genetic counselor who has more than 25 years of clinical experience in laboratory, prenatal, adult, and cancer genetics. For one insurer, she worked as a medical policy administrator and genetic counselor.

Lewis. "If an out-of-network lab offers a genetic test that no in-network lab offers, then the provider portal is likely to approve the order, despite the fact that the lab is out of network."

In conclusion, Lewis explained that Anthem and AIM sought to design a pre-approval process for genetic tests that would meet the needs of patients, providers, and labs. "What's the common ground in this whole space?" she asked. "Labs want people to order genetic tests and get paid, and physicians want access to good testing and they don't want their patients to be liable for large out-of-pocket costs. As a health insurer, we want patients to have access to good useful genetic testing that will affect medical decision making."

The design of Anthem's Genetic Testing Solution is intended to be win-win for all parties, Lewis added. "The goal is that, when a provider gets an authorization for a certain lab for a certain genetic test, the lab will be reimbursed for that test," she observed. "That avoids the nightmare of whether and how much the lab will be paid.

"Labs want to know upfront that they will be guaranteed payment and they want to know how much they're going to get paid," she said. "The Genetic Test Solution and its pre-authorization process are designed to provide that certainty." **TDR**

—Joseph Burns

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