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Personalized Medicine in 2019: Options Increasing But Are They Reaching Patients?

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NEW YORK – In 2019, the field of personalized medicine continued to grow with the market launch of more than two dozen drugs targeting novel genomic alterations and numerous genetic tests to determine whether patients are at risk for serious diseases like cancer, and whether they are likely to respond to therapy.

The mechanisms of these newer drugs and the algorithms underlying the latest tests reflect the field's increasing understanding of complex disease biology. "2019 has been a pivotal year and we are seeing exponential growth in precision medicine," said Jordan Clark, chief commercial officer at diagnostics data analytics company Diaceutics.

Two years ago, Diaceutics estimated that 40 percent of US Food and Drug Administration-approved drugs fell into the personalized medicine category. But in 2020 and 2021, the firm is projecting that the number of new precision medicine drug approvals will outnumber the non-precision medicine therapies.

However, with more drugs and tests to choose from, the market dynamics are also getting increasingly complex. Diaceutics' data also shows that many patients are missing out on the chance to receive personalized drugs due to inefficiencies in the testing market, technological limitations in the healthcare system, and lack of physician education.

Meanwhile, in contrast to the continued growth in clinical genetics, the direct-to-consumer genetics market may be showing signs of a slowdown. Some analysts believe this is perhaps due to saturation by early adopters or to increasing concerns about privacy issues.

Several companies in the broader consumer genomics space, including firms providing testing for entertainment and health risks, halted operations. National Geographic stopped sales of its ancestry DNA kits and is ending services altogether in 2020. Veritas Genetics, which targeted the consumer market for health related genetic testing through more affordably priced whole-genome sequencing and interpretation services, announced it was stopping US operations because a planned financing fell through.

Meanwhile, several companies made moves to expand their reach in this space. Ancestry and MyHeritage, which until 2019 were focused on genetic genealogy, moved into health-related testing, while traditional clinical genetics companies, like Invitae, embraced a consumer-facing model. Helix, which launched two years ago promising to change how consumers interacted with their DNA, scaled back the offerings in its "apps marketplace" and decided to focus on partnering with healthcare systems to integrate genomics into longitudinal population health studies.

The largest of these, the National Institutes of Health's All of Us Research Program, made some headway in terms of enrolling 1 million participants in 2019, but did not begin genomic testing of patient samples as it had hoped to. The program has said it will start returning test results to participants next year, but before it can do so, the FDA must approve its investigational device exemption application. The agency determined that because the program planned to return results on heritable disease risk and pharmacogenetics, an IDE submission would be needed.

Pharmacogenetic tests without FDA approval were a special area of concern for the agency this year, as it sent a warning letter to Inova Health System's genomics lab and began reaching out to commercial labs asking why they were marketing tests without premarket review. However, industry players pushed back, criticizing that the agency's actions lacked transparency, consistency, and was counter to its mission to protect the public health.

Stakeholders across industry, academia, and advocacy were also in agreement that the Centers for Medicare & Medicaid Services' proposal to limit coverage for next-generation sequencing panels to assess germline cancer risk in early-stage cancer patients would result in public health harm. Significant stakeholder pushback convinced CMS to reopen its national coverage determination and take in public comments, but this controversy is still not resolved. Toward the end of the year, CMS issued a draft NCD that no longer limits coverage for germline NGS testing based on disease stage, but now requires that breast and ovarian cancer risk tests have FDA clearance or approval. Unfortunately, stakeholders have pointed out that no test on the market meets all of CMS proposed criteria for national coverage.

Ellen Matloff, a certified genetic counselor and CEO of health technology firm My Gene Counsel, flagged both the FDA's approach to regulating PGx testing and CMS' reimbursement proposals for germline NGS for hereditary cancer risk as perhaps well-intentioned misunderstandings on the part of government officials that nonetheless represent setbacks for personalized medicine in 2019. "Some of these mistakes at the FDA level and now at the insurer level are embarrassing and very expensive, not only in dollars but in terms of reputation," she said. "For these agencies to be making ... factual errors, it just looks terrible in the age of precision medicine."

'Find the Gems'

By GenomeWeb's count, in 2019 the FDA approved 27 personalized drugs — seven new molecular entities and 20 expanded indications of previously approved drugs — compared to 25 approvals last year and 19 in 2017 (*see charts below; larger versions here and here*).

There were several firsts in this list. For example, one in five advanced bladder cancer patients with FGFR alterations for the first time has a personalized option in erdafitinib (Janssen Pharmaceuticals' Balversa); while 40 percent of hormone receptor-positive, HER2-negative breast cancer patients with PIK3CA mutations can now receive alpelisib (Novartis' Piqray). Men for the first time were included in labeling for the personalized breast cancer drug palbociclib (Pfizer's Ibrance).

There were new personalized drugs for cystic fibrosis and Duchenne muscular dystrophy, and expanded approval of a drug for an inherited condition that causes high cholesterol. Still, as in other years, oncology drugs remained the force driving up the personalized medicine approval count, comprising around three-fourths of new and expanded drug indications.

"More and more we're seeing the era of precision medicine where drugs are being approved with a specific biomarker," said Razelle Kurzrock, director of the Center for Personalized Cancer Therapy at the University of California Moores Cancer Center. "These drugs have much higher response rates than what we were previously accustomed to ... because we narrowed down the population of patients to whom they're given, and we don't give them to everybody indiscriminately."

For example, 2019 saw the approval of the third pan-cancer therapy with entrectinib (Genentech's Rozlytrek). Although NTRK fusions occur in less than 1 percent of solid tumors, in the studies submitted for FDA approval, 57 percent of advanced cancer patients saw their tumors shrink and 61 percent experienced tumor shrinkage for nine months or longer. "These are incredible response rates in advanced cancer," Kurzrock said, noting though that if these drugs had been tested in an all-comer population, they'd show little activity and be deemed "worthy of the trashcan."

Entrectinib also happens to be the second drug for this rare subset of patients, after the approval of larotrectinib (Bayer and Loxo Oncology's Vitrakvi) last year for advanced, NTRK-positive solid tumors. Despite being indicated for a small patient population, larotrectinib and other personalized medicine indications being developed by Loxo were attractive enough for Lilly to pay $8 billion for the specialized biotech in 2019, and for Bayer to exercise its rights to gain control of the drug and LOXO-195, an experimental treatment for those who have developed resistance to TRK inhibitors.

These highly active personalized therapies have a better shot at coming to market now than they did a decade ago, Kurzrock observed, because the FDA has been more willing to approve drugs for rare populations based on response rates and single-arm studies when there is data showing the drug is active. Without the requirement to do

a large, randomized trial, drugmakers aren't dropping these rare-indication drugs like they would have a decade ago, Kurzrock said.

Large pharma companies will continue to snap up small, specialized biotechs with these types of personalized medicine assets in coming years, Diaceutics' Clark predicted. "Small biotechs [will be] doing a lot of heavy lifting on the innovation and R&D side, then to be supported by big pharma with M&A later," he said.

Another example of this in 2019 was GlaxoSmithKline's acquisition of Tesaro for around $5 billion, which gave it the PARP inhibitor niraparib (Zejula). Toward the end of the year, the FDA expanded the indication for niraparib to heavily pretreated ovarian cancer patients whose cancer cells have impaired DNA repair capabilities, as detected by a companion test.

"I suspect that the groups advising the [executives] of these large [pharma] companies are saying you need to go on a hunt for these important gems," said Diaceutics CEO Peter Keeling. "And these gems are often accompanied by new biomarkers and new tests."

Complex biomarkers

The year also saw the emergence of biomarker tests, such as Myriad Genetics' myChoice CDx, which assesses homologous recombination deficiency (HRD) in ovarian cancer patients and determines if they're likely to respond to niraparib. The FDA-approved companion diagnostic goes beyond detecting BRCA1/2 mutations in patients, and analyzes other genes and pathways involved in DNA repair.

According to Clark, however, there's a lot of confusion in the field right now about how to define HRD, and this may limit its adoption. "If you ask five pathologists what HRD is, you get five different definitions, not just on the cutoffs but which genes are used, does it include somatic and germline [mutations], is it large rearrangements and loss of heterozygosity," he said. "Until we set out that definition and standardize and harmonize [testing approaches], I don't think physicians are going to know how to use it."

The year also didn't bring the field much closer to a biomarker that would neatly separate responders and non-responders to immunotherapy, though there were high hopes that tumor mutational burden would be this biomarker. Studies yielded contradictory results on the ability of TMB to predict response to immunotherapy, and it appears now that the biomarker may be difficult to implement in the clinic across tumor types. "TMB has not lived up to the hype that there was originally around it," Clark said. "Some of the data that we've seen come out [this year] ... hasn't really proven it to be the biomarker that we thought we needed for immunotherapy."

As a result, PD-L1 expression, even though it's not ideal, continued to be used. The FDA expanded the indications of several immunotherapy drugs into new cancer indications, using PD-L1 expression status to identify patients most likely to benefit. Despite many labs reporting TMB and the availability of an FDA-cleared test, TMB hasn't overtaken PD-L1 testing, according to data collected by Diaceutics. "Actually when you look at implementing [TMB] and its viability, it was always going to be a very hard test to implement, which was always going to impact its adoption, limiting its use in the real world," Clark said.

TMB and HRD are part of a steady move toward more complex predictive biomarkers in oncology, but things are moving in the right direction, as far as Kurzrock is concerned, if precision medicine is to extend cancer patient's' lives. "It is getting more complicated but that's a good thing in many ways, because cancer is complicated," she said. "When we had simple tools, we were probing a complicated disease and thinking we understood it, when we only understood a very little piece of it."

However, not all personalized drugs in the future may rely on a companion diagnostic to identify best responders. For example, several industry observers cited the new gene therapy for spinal muscular atrophy, onasemnogene abeparvovec-xioi (AveXis/Novartis' Zolgensma), as an example of a precision drug that came to market in 2019. However, because the drug doesn't require a predictive molecular diagnostic to determine who should receive it, the therapy didn't make GenomeWeb's list.

SMA patients have a non-functioning SMN1 gene. Zolgensma works by delivering a working copy of the SMN1 gene to target motor neurons using a genetically engineered adeno-associated virus, AAV9. The website for the

drug notes that an AAV9 antibody test may be needed to gauge whether the child has built up anti-AAV9 antibodies and therefore cannot received the gene therapy. "If your body has an immunity to adenovirus, you have very high [levels of] antibodies against it, which means your body attacks the gene therapy, and it can't deliver its payload … and provide the change in DNA," Clark said.

The story of this drug has been tainted by allegations that AveAxis manipulated data submitted to the FDA. Regardless, Clark said that drugs like onasemnogene are now part of a growing list of personalized drugs that Diaceutics is tracking, which may not have an FDA-approved companion test but rely on diagnostics to differentiate who should get treatment.

Reaching patients

Despite the availability of more drugs and tests, Diaceutics' research also suggests these new drugs may have a tough time reaching patients due to inefficiencies in the diagnostics market and lack of physician education. In oncology, for example, Diaceutics' data shows that when the companion test launch is not appropriately planned, only around 50 percent of patients eligible for testing for precision treatments are getting this analysis.

The challenge is evident in lung cancer, which has seen major advances in personalized medicine in recent years. Despite the availability of several new molecularly targeted treatment options and guidelines stating that all lung cancer patients should be tested for mutations in EGFR, ALK, and ROS1, the majority of oncologists, surgeons, and pathologists who took part in an international survey said that less than 50 percent of lung cancer patients were getting such testing. They cited a number of challenges with testing, including cost, sample quality issues, and turnaround time. More than a third of the respondents also said they had difficulty understanding the test results.

Part of the problem is that no entity has taken up the responsibility of educating the providers about the increasingly crowded landscape of predictive biomarkers that may be important for treatment selection. Diaceutics has consistently encouraged its pharma clients to get involved in educating doctors and the broader healthcare ecosystem about the biomarkers and tests its drugs rely on to get to the right patients. While some drugmakers have invested in online educational resources, pharma hasn't yet done the heavy lifting necessary in this regard and is losing billions in revenue as a result, Diaceutics research shows.

"Hundreds of millions of dollars are spent on the education and promotion of the arrival of a new drug. We've seen that over the past 40 years," Keeling said. "The question is who owns that in diagnostics? Labs don't necessarily own the education of a biomarker and diagnostic companies can't afford to own it because they don't have enough launch dollars."

Even when physicians are aware of the available personalized options, many advanced cancer patients miss out on the chance to get treated due to insufficient tissue samples or because they can't endure a biopsy. However, 2019 saw the market availability of a number of liquid biopsy tests that can gauge mutations from blood samples.

For example, with the approval of alpelisib for PIK3CA-mutated advanced breast cancer, the FDA also approved Qiagen's Therascreen PIK3CA RGQ PCR kit as a companion diagnostic to identify patients with PIK3CA mutations from tissue and blood samples. The New York State Department of Health approved Memorial Sloan Kettering's MSK-ACCESS, a circulating cell-free DNA test that will be used when patients can't provide tumor tissue for genomic profiling or when the cancer center's tumor profiling test is uninformative.

Inivata achieved local Medicare coverage for its liquid biopsy lung cancer test for gauging mutations in EGFR, ALK, ROS1, and BRAF when tissue-based genomic profiling is not possible and when patients are progressing on EGFR inhibitors. And earlier this month, Guardant Health also received local Medicare coverage for its Guardant360 liquid biopsy test when used to guide therapy decisions for patients with solid tumors who have insufficient or unavailable tumor tissue for testing.

As more personalized drugs come to market and the testing landscape becomes more complex, decision support tools are becoming necessary to provide doctors with the timely information they need to treat patients. However, many healthcare systems' electronic health records are not able to provide physicians with such support, said

Matloff, whose company, My Gene Counsel operates a digital platform that aims to provide such assistance to doctors.

"It's challenging for a health system to pull up not only all of its patients with cystic fibrosis, but all cystic fibrosis patients who have one or two [copies of the] delta F508 mutation," said Matloff as an example. "These health systems often have those test results buried in a saved PDF somewhere within the EHR rather than saved as a discrete variable." This makes it difficult to identify patients who might benefit from a new biomarker-specific drug.

This problem hasn't gone unnoticed by technology providers. In 2019, there was a proliferation of new platforms and virtual molecular tumor boards to help doctors make sense of complex genetic test reports in the context of patient care. According to one market research report, the market for precision medicine software is growing at an annual rate of 13.5 percent and is expected to go from a $870 million market in 2017 to $2.72 billion by 2026. This growth is being driven by advances in big data technologies, the growing number of cancer patients, and greater government investment in precision medicine initiatives.

Although the NIH's All of Us Research Program hasn't yet begun returning genetic test results to participants, in preparation for this, the NIH awarded a grant to genetic testing firm Color to set up a counseling resource to support all those who agree to testing within the program. As an experienced genetic counselor, Matloff also sees a growing need for digital solutions to provide education and counseling support to people and providers as access to genetic information grows through the proliferation of large-scale population health studies like All of Us.

Regulation and reimbursement

In 2019, the issues in regulation and reimbursement impacting the personalized medicine field remained much the same, with no meaningful progress made in reforming oversight of lab-developed tests, while pricing pressures continued to plague the diagnostics sector.

In December 2018, legislators released a draft bill, called the VALID Act, incorporating the FDA's ideas for creating a new regulatory framework for all *in vitro* clinical tests, including LDTs. A few days later, the US government shut down and remained closed through most of January 2019. A few months later, then-FDA commissioner Scott Gottlieb, who had championed a lot of the ideas in VALID — such as a precertification program to streamline the test approval process and lessen the regulatory burden on labs — resigned.

Since then, the draft bill hasn't made much progress and its status is unclear. However, the agency made clear that regardless of congressional action on a new legislative framework, it believes it has the authority to regulate LDTs and began contacting PGx testing labs without FDA approval. The agency's actions have alarmed lab industry stakeholders, who have characterized the agency's actions as "backdoor" attempts to regulate LDTs. Some industry players are banding together to pen a Citizen Petition and ask the FDA to stop its "illegal" attempts to regulate labs.

On the reimbursement front, diagnostics companies continued to face significant pricing pressures throughout the year. Private payors are continuing to focus on reining in test spending through the use of lab benefit managers, prior authorizations, and preferred lab networks. These policies taken together made it seem like payment got much harder, not better, for the diagnostics industry in 2019, reflected reimbursement expert and consultant Bruce Quinn. "There seems to be a lot of bad news in the industry," he said.

Anthem, for example, put in place a "rate-alignment" strategy late last year, aiming to pay the same price for tests regardless of the type of lab performing testing. This policy had a significant impact on clinical labs in the last 12 months, particularly labs within hospitals, which have historically enjoyed higher rates than large independent labs. Anthem announced changes to lab rates in more than a dozen states, and many of the rates represent as much as a 70 percent cut from previously negotiated prices. Industry observers are concerned that other insurers might follow Anthem's example.

However, the lab industry was successful at the close of the year with the passage of the LAB Act, which will delay for a year lab reporting of payment data that the Centers for Medicare & Medicaid Services uses to price tests. Under the Protecting Access to Medicare Act, labs were required to report payment data between Jan. 1, 2020 and March 31, 2020, and rates based on that data were slated for implementation starting Jan. 1, 2021. Many industry

players found the reporting process too complex, and complained that CMS data collection and calculation methods were resulting in steeper-than-intended cuts. This reporting process is now halted while the National Academy of Medicine identifies ways to improve it.

Meanwhile, some labs are seeing FDA approval as a path to better reimbursement prospects for their NGS tests for guiding cancer therapies. There is certainly more incentive to pursue FDA review now that CMS provides national Medicare coverage for NGS tests that are approved by the agency as companion diagnostics for guiding treatment decisions for advanced cancer patients. Companies like Caris Life Sciences and Guardant have chosen to take this route.

However, many labs still feel the FDA approval process to be onerous and cost prohibitive. In its latest draft national coverage determination on germline NGS assessment for inherited risk for breast and ovarian cancer, CMS has said that tests must have FDA approval or clearance. No currently marketed NGS germline test for breast and ovarian cancer risk has FDA approval or clearance, and therefore no test would qualify for coverage. As such, a chorus of stakeholders have asked CMS to do away with this requirement.

"That [policy] has been a real mess up. CMS has tried to be too simplistic in a very complex world of NGS," said Diaceutics' Clark. "If CMS is not even getting it right in their guidance, how can anybody else expect to get it right?"

2019 Personalized Drug Approvals - New Drugs

Approval Date	Drug	Company	Indication	Companion Dx[1]	Other Dx[2]
4/12/2019	erdafitinib (Balversa)	Janssen Pharmaceuticals	locally advanced/ metastatic bladder cancer progressed on platinum chemo; FGFR3 or FGFR2 alterations	Qiagen therascreen FGFR RGQ RT-PCR Kit	
5/24/2019	alpelisib (Piqray) and fulvestrant	Novartis	advanced or metastatic breast cancer; hormone receptor-positive; HER2 negative; PIK3CA mutated	Qiagen therascreen PIK3CA RGQ PCR Kit; Foundation Medicine FoundationOne CDx	
8/15/2019	entrectinib (Rozlytrek)	Genentech	adults and adolescents with solid tumors and without alternatives; NTRK fusions		Yes
8/15/2019	entrectinib (Rozlytrek)	Genentech	metastatic non-small cell lung cancer; ROS1 positive		Yes
10/21/2019	elexacaftor/tezacaftor/ ivacaftor and ivacaftor (Trikafta)	Vertex Pharmaceuticals	12 years or older with cystic fibrosis with at least one F508del mutation in CFTR gene		Yes
12/12/2019	golodirsen (Vyondys 53)	Sarepta Therapeutics	Duchenne muscular dystrophy with confirmed mutation in dystrophin gene amenable to exon 53 skipping		Yes
12/20/2019	fam-trastuzumab deruxtecan-nxki (Enhertu)	Daiichi Sankyo/AstraZeneca	unresectable or metastatic breast cancer after at least two prior anti-HER2-based regimens; HER2-positive		Yes

1 FDA cleared/approved tests required for the safe and effective use of a drug

2 Other tests for identifying patient population that can receive treatment

This list highlights personalized drugs that the FDA approved in 2019 with a companion diagnostic, or drugs that rely on other molecular diagnostics to identify who should receive them. This list does not include drugs that may be considered personalized based on other criteria.

2019 Personalized Drug Approvals - Expanded Indications					
Approval Date	**Drug**	**Company**	**Indication**	**Companion Dx[1]**	**Other Dx[2]**
1/30/2019	pembrolizumab (Keytruda) and pemetrexed injection	Merck	first-line metastatic, non-squamous, non-small cell lung cancer; without EGFR or ALK alterations		Yes
2/28/2019	trastuzumab and hyaluronidase-oysk (Herceptin Hylecta)	Genentech	early breast cancer; HER2 positive	various	
3/8/2019	atezolizumab (Tecentriq) and nab-paclitaxel	Genentech	adults with unresectable locally advanced or metastatic triple-negative breast cancer; PD-L1 positive	Roche Ventana PD-L1 (SP142) Assay	
3/11/2019	ribociclib (Kisqali) and fulvestrant	Novartis	advanced/metastatic, postmenopausal breast cancer as initial endocrine therapy or after progression; HR positive; HER2 negative		Yes
4/4/2019	palbociclib (Ibrance) and an aromatase inhibitor or fulvestrant	Pfizer	advanced or metastatic breast cancer; men and women; HR positive; HER2 negative		Yes
4/11/2019	pembrolizumab (Keytruda)	Merck	stage III unresectable non-small cell lung cancer; can't receive chemoradiation or metastatic NSCLC; without EGFR or ALK alterations; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
4/29/2019	ivacaftor (Kalydeco)	Vertex Pharmaceuticals	cystic fibrosis patients 6 months and older; one mutation in the CFTR gene responsive to ivacaftor based on clinical and/or *in vitro* assay data		Yes
5/2/2019	ivosidenib (Tibsovo)	Agios Pharmaceuticals	75 years or older, newly-diagnosed acute myeloid leukemia; cannot receive induction chemotherapy; IDH1 mutation	Abbott RealTime IDH1	
5/3/2019	ado-trastuzumab emtansine (Kadcyla)	Genentech	adjuvant treatment of early breast cancer with residual invasive disease after neoadjuvant taxane/trastuzumab based treatment; HER2-positive	various	
5/10/2019	ramucirumab	Eli Lilly	hepatocellular carcinoma		Yes

	(Cyramza)		treated with sorafenib and alpha fetoprotein of ≥400 ng/mL		
5/16/2019	pitavastatin (Livalo)	Kowa Pharmaceuticals America	8 years or older with heterozygous familial hypercholesterolemia to reduce elevated total cholesterol, LDL-C, and Apo B		Yes
6/10/2019	pembrolizumab (Keytruda)	Merck	first-line metastatic or unresectable, recurrent head and neck squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
6/21/2019	tezacaftor/ivacaftor and ivacaftor (Symdeko)	Vertex Pharmaceuticals	cystic fibrosis ages 6-11 years; two copies of the F508del CFTR mutation or one mutation in CFTR responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence		Yes
7/30/2019	pembrolizumab (Keytruda)	Merck	recurrent locally advanced or metastatic esophageal squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
8/28/2019	ledipasvir and sofosbuvir (Harvoni)	Gilead Sciences	patients 3 years and older, weighing at least 17 kg, with chronic hepatitis C virus; genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; genotype 1 infection with decompensated cirrhosis, in combination with ribavirin; genotype 1 or 4 liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin		Yes
8/28/2019	sofosbuvir (Solvadi)	Gilead Sciences	patients 3 years or older, weighing at least 17 kg, with chronic hepatitis C virus: genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis, in combination with ribavirin		Yes
9/17/2019	pembrolizumab (Keytruda) and lenvatinib (Lenvima)	Merck/Eisai	advanced endometrial carcinoma progressing after systemic therapy and cannot receive surgery or radiation; not microsatellite instability high and mismatch repair deficient		Yes
10/23/2019	niraparib (Zejula)	GlaxoSmithKline	advanced ovarian, fallopian	Myriad Genetics	

			tube, or primary peritoneal cancer; received at least three prior chemotherapy regimens; BRCA1/2 mutation or homologous recombination deficiency positive	myChoice CDx	
12/3/2019	atezolizumab (Tecentriq) with paclitaxel protein-bound and carboplatin	Genentech	first-line metastatic non-squamous non-small cell lung cancer; without EGFR or ALK alterations		Yes
12/30/2019	olaparib (Lynparza)	AstraZeneca/Merck	maintenance treatment of platinum-responsive, metastatic pancreatic cancer; germline BRCA1/2 mutations	Myriad Genetics BRACAnalysis CDx	
1 FDA cleared/approved tests required for the safe and effective use of a drug 2 Other tests for identifying patient population that can receive treatment					
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