

Exact Sciences' Telehealth Program a Positive Over Time

Companies: EXAS, PFE

May 4, 2020

Report Type: Initial Coverage Previously Covered Full Report Update Rating: **3.5/5**

Research Question:

What effect will Exact Sciences' telehealth efforts have on Cologuard test numbers during and after COVID-19 quarantines?

Summary of Findings

- Exact Sciences Corp.'s (EXAS) online [Cologuard](#) ordering and telehealth program is not well known, although it is viewed positively by those that do know of it. It is not expected to drive significant test volume but sources said it will benefit test utilization over time. Cologuard is seen as being well positioned as an in-home test that keeps patients out of medical offices as preventive health services begin to ramp back up.
- Sources said routine preventive healthcare has all but shut down and patients are not thinking about screening for colorectal cancer (CRC) during the COVID-19 pandemic and stay-at-home requirements
- As medical practices reopen, there will be a backlog of CRC screenings, including Cologuard and colonoscopies. Cologuard volume is expected to spike and then resume its growth trend. One source said Cologuard could be offered as an option to patients with no family history of CRC that are in the backlog queue for colonoscopies as part of their routine preventive healthcare. Another source noted that Exact Sciences is calling patients that have not followed through with their Cologuard test and encouraging them to do so.
- Exact Sciences [preannounced](#) strong Q1 results. However, as a direct result of COVID-19, Cologuard test volume declined 36% year to year in the last 16 days of March and 63% for the first 20 days of April.
- Blueshift Research's [Oct. 16, 2019](#), and [Feb. 15, 2019](#), Exact Sciences reports were overwhelmingly positive regarding the company's continued growth. Given the uncertainties of the present economic environment, we are rolling back our rating from 4 out of 5 to 3.5 out of 5. Growth is still expected as medical practices reopen, but Cologuard test volumes will take time to rebuild.
- Two physicians discussed their concerns with Exact Sciences' direct-to-consumer (DTC) advertising, which they characterized as misleading or misinforming. A source representing a pharmacy benefit manager (PBM) said insurance companies will be looking at new testing options and doing due diligence to determine sensitivity, selectivity, and economy.
- The rapid utilization of telehealth during the COVID-19 pandemic is expected to have a lasting and positive effect on the delivery of healthcare. Sources noted the relaxing of regulations to allow its use, patient and caregiver willingness to use it, third-party payers' improved reimbursement rates, and the promise it offers for more efficient and improved healthcare delivery and a new revenue stream for medical practices, which will drive wide adoption following the pandemic.

	Telehealth Impact on EXAS During Shutdown	Telehealth Impact on EXAS After Shutdown	Overall Telehealth Future
Physicians and Medical Professionals	➔	➔	⬆️
Medical Testing Sales Channel	➔	➔	⬆️
Industry Specialists	➔	➔	⬆️

Update: Exact Sciences Corp.'s Cologuard

Background

In Blueshift Research's [Oct. 16, 2019](#), and [Feb. 15, 2019](#), Exact Sciences reports sources said Cologuard has a significant runway for growth among the one-third (about 20 million people) of 50-year-old patients who refuse or cannot tolerate a colonoscopy. Sources also expected the expanded indication of Cologuard for screening 45- to 49-year-olds to drive additional sales.

Exact Sciences [reported](#) continued growth in Q4 but missed both earnings and revenue expectations. Cologuard test volume was 477,000, an increase of 63%, and the average Cologuard-recognized revenue per test was \$481 vs. the average test cost of \$123, an improvement of \$6. Combined revenue for both Exact Sciences and Genomic Health, the California company Exact Sciences acquired last year in a \$2.8 billion deal, was up 60% year to year. Exact Sciences posted earnings of \$77.9 million, or \$0.54 per diluted share, which also beat projections of a quarterly loss of \$0.34 per share.

Highlights for Exact Sciences from Q4 and early Q1 2020 [include](#):

- A significantly expanded TAM to \$20 billion due to the acquisition of Genomic Health and the expanded Cologuard label for screening 45- to 49-year-olds for CRC.
- The creation of a 1,000-person sales team, which includes Pfizer Inc.'s (PFE) sales team working to promote Cologuard and a specialized group of 60 professionals focused on selling to gastroenterologists.
- Progress on a next-gen Cologuard test showing new markers with improved specificity, while maintaining a high level of sensitivity in comparison to the current version. Exact Sciences has initiated a 10,000-patient prospective trial to validate the new test's performance.
- Positive data presented on its liver cancer test, which it expects to launch in the second half of 2020.
- Agreements to acquire [Paradigm](#) and Viomics, companies with deep DNA sequencing capabilities. Paradigm provides a therapy selection test for late stage cancer patients; Viomics provides critical sequencing and biomarker discovery capabilities.

On March 15, Exact Sciences published a letter addressing the coronavirus. Employees that could work from home were asked to do so and patient-critical work teams were expected to continue to operate normally, following all safety procedures and practices. On March 19, Exact Sciences suspended field-based, face-to-face interactions by its sales force and said the sales team will serve healthcare providers via telephone and online technologies. The company highlighted that it was well positioned to continue delivering Cologuard tests via telehealth technology and at-home sample collection. Exact Sciences also withdrew its Q1 and full year 2020 guidance. On March 30, it was announced that Exact Sciences had joined a public-private partnership to double the COVID-19 testing capability in Wisconsin.

On April 2, Exact Sciences [highlighted](#) that, through a telehealth provider, its Cologuard test is available without a visit to a doctor for a prescription. Kevin Conroy, Exact Sciences chairman and CEO, said, "Cancer doesn't stop for anything. As the country faces a pandemic, we are letting people know they can request Cologuard online from a healthcare provider, without an office visit. While Americans are at home trying to prevent the spread of COVID-19 in their communities, they can address another pressing public health issue and get screened for colorectal cancer."

Current Research

Blueshift Research assessed how Cologuard testing volumes would be impacted during and after COVID-19 quarantines. We employed our pattern mining approach to establish four independent silos, comprising 11 primary sources (including seven repeat sources) and two secondary sources focused on Cologuard testing volumes. Interviews were conducted April 20–29.

- 1) Physicians and medical professionals (6)
- 2) Medical testing sales channel (3)
- 3) Industry specialists (2)
- 4) Secondary sources (2)

Update: Exact Sciences Corp.'s Cologuard

Silos

1) Physicians and Medical Professionals

All six sources said Exact Sciences will be negatively impacted by COVID-19 stay-in-home orders and the cancellation of all but emergency medical procedures. The ability for patients to order a Cologuard test online via telehealth is expected to have minimal impact in the short run, but over time will contribute to an increase in test volume. Cologuard use will increase as medical practices reopen, as it is a valued CRC screening tool, although two sources did complain about Cologuard's DTC advertising campaign, which does not address the tests sensitivity. One source said Cologuard could be used to ease the colonoscopy backlog that is building. Patients without a family history of CRC scheduled for preventive screenings might be offered a Cologuard test to reduce the backlog. Use of telehealth has expanded during the shutdown, aided by reduced regulations, increased third-party reimbursement, and increased patient acceptance. Sources expect the use of telemedicine to continue to expand following the reopening of medical practices. Telehealth demand will be driven by some patients' reluctance to go to medical facilities out of fear of contracting the coronavirus, the efficient and improved delivery of some healthcare services, and the revenue generating opportunity it offers.

1) Practicing gastroenterologist also conducting research in population-based studies of CRC and hospital-based studies of colorectal adenomas (precursors to most CRCs)

This nationally and internationally known gastroenterologist is working in a large academic teaching and research university-based practice in the Southeast. While his practice, and that of the entire GI Division, is largely closed (colonoscopies have dropped from 100 per day to 10 per day due to the pandemic) he sees Cologuard and telemedicine as game changers in the future. There is a very large backlog of colonoscopy exams growing as a result of the pandemic and he believes that Cologuard and telemedicine will be strong solutions to managing this problem. He feels they will also change the way their outpatient practices will operate by making them more efficient and responsive to patient needs. He sees Exact Sciences as an excellent investment opportunity given the strong role that Cologuard will play in the near future.

COVID-19 Impact on Exact Sciences

- "Still the predominant way of requesting Cologuard is through primary care providers. No one knows about the new online development with Cologuard."
- "I am not aware that they were doing COVID-19 testing."
- "I am not getting contacted by any sales reps currently."
- "Prior to the shutdown, I was scheduled all the way out to June for colonoscopies. When this is all over, there will be a huge backlog of exams that need to be done and the screening people will get bumped. Using Cologuard will make a lot of sense for a couple groups of patients: for screening patients who would have to wait many months, for patients who are still concerned about going into clinic settings (COVID-19 PTSD is real), and for patients who don't want to wait for the 7 to 10 years between colonoscopies (new, longer [American Gastroenterological Association] guidelines that were recently released)."
- "Using [Epic \[Systems Corp.\]](#) to order testing is a great idea for the family medicine and general internal medicine people. However, Epic does not streamline anything. It's always much harder than it needs to be with Epic."
- "Already, many patients can't figure out how to use the Epic capability because there are so many steps that they have to go through just to get it to start, so, for them, we just do it over the phone."

Impact of Online and Telemedicine on Exact Sciences

- Did not discuss.

When this is all over, there will be a huge backlog of exams that need to be done and the screening people will get bumped. Using Cologuard will make a lot of sense for a couple groups of patients: for screening patients who would have to wait many months, for patients who are still concerned about going into clinic settings, ... and for patients who don't want to wait for the 7 to 10 years between colonoscopies.

Practicing gastroenterologist also conducting research in population-based studies of CRC and hospital-based studies of colorectal adenomas

Update: Exact Sciences Corp.'s Cologuard

Cologuard Use

- “I suspect that the pandemic has produced a dramatic decrease in all healthcare volumes—visits and sales. But this is a good product and I see that it will increase rapidly after the pandemic.”
- “I don’t use Cologuard. By the time the patient gets to me there is already a serious issue going on.”
- “This is the same, currently, in the rest of the division. But we may need to start recommending this for our screening patients to keep them out of the clinic and to get them results in a more timely way than we will be able to in the future.”

Telehealth

- “The entire Department of Medicine, including the GI Division, is using telemedicine through Epic. All the providers were trained last week on how to use it.”
- “By using Epic, we get paid the same as if it was a face-to-face visit. If we use the telephone, or FaceTime, or Zoom [Video Communications Inc./ZM], the reimbursement is about 10% of the face-to-face amount.”
- “Telemedicine will continue very actively after the pandemic. For example, today I saw a woman who lives two hours away. She has a genetic condition and has been a patient of mine for several years. There is no reason that I need to physically see her and for her to drive a four-hour roundtrip for her to see me. So it’s perfect for patients like her.”
- “In the future, for very busy outpatient operations like ours, telemedicine will be a great way to manage clinic volumes. We’ll only need to see patients who need to be seen in person. The rest can be seen using the Epic telemedicine capability. That will unclog the clinics and get patients seen more quickly.”

Miscellaneous

- “As an investment, Exact Sciences seems very compelling to me. This is largely because it will be a good mechanism to cut down the huge backlog in colonoscopy exams that is growing as a result of the virus.”

2) Family nurse practitioner in private practice; repeat source

This clinician plans to begin prescribing Cologuard again in May when her practice fully resumes. She expects an “uptick” in Cologuard tests then for people who are behind in their screening. Her Cologuard prescriptions before the pandemic were between one to five each month. Exact Sciences’ telehealth program will increase Cologuard testing during and following the pandemic because people will be more comfortable with telehealth from using it for their medical care.

COVID-19 Impact on Exact Sciences

- “Right now, our practice is greatly impacted [by the pandemic] because we are only seeing mostly urgent walk-in patients and we have, like most people, started to do some regular visits using telehealth. ... So I would say [COVID-19] is having a pretty big impact, and we are not in a hard-hit area. I can’t imagine what it’s like in some of those places.”
- “Exact Sciences has a big science staff. If they could find a way to do the [COVID-19] testing for the presence of the disease and the antibodies, that could certainly help the country with the ability to reopen, I think, because we don’t know who is actually carrying [the virus], or who has it, or who had it, unless they are really sick.”
- “I think the options may be limited for doing regular colonoscopy and other types of screening [during the pandemic shutdown]. So Cologuard may actually get to [40% of CRC screening] because it’s more accessible to individuals than colonoscopy, or maybe mailing in a stool sample that has to be tested in another way. So I think that is a positive for Cologuard because no one wants to have to go out and do anything that they don’t really have to do right now.”
- “[Whether physicians are doing colonoscopies now] just depends on where you are in the country. Some places are still open and doing those sorts of things, and other places are totally shut down.”
- “I believe I have received some online information from either Exact Sciences or Pfizer [during the quarantine].”

Impact of Online and Telemedicine on Exact Sciences

- “[Exact Sciences’ telehealth program] might help people who have concerns or who have been told about Cologuard in the past and didn’t follow up. It will give them an opportunity to get [Cologuard] while they are sitting there thinking about it because many people have more time on their hands now than they did in their fast-paced lives before.”

I think [Exact Sciences’ telehealth effort will increase the number of Cologuard tests during and after the pandemic] because people will be more comfortable with telehealth.

Family nurse practitioner in private practice

Update: Exact Sciences Corp.'s Cologuard

- “I think that [the sales volume Exact Sciences could achieve due to telehealth] just depends on the location and how comfortable people will be using telehealth. I think telehealth is increasing because more people are being forced to use it, and they may become more comfortable with it.”
- “I think [Exact Sciences’ telehealth effort will increase the number of Cologuard tests during and after the pandemic] because people will be more comfortable with telehealth.”

Cologuard Use

- “I only see acutely ill patients right now. [Before the pandemic], I’d say my Cologuard prescriptions were flat, at about one to five per month.”
- “We are not [doing any Cologuard prescribing now]. We are going back to our regular practice at the beginning of May. I think that more people will come in then because they will be behind, so [Cologuard] may have a little uptick.”

Telehealth

- “We just started doing telehealth visits last week. We are doing both acute and chronic care visits on telehealth.”
- “Once people kind of get a taste of the convenience of telehealth, I think they will like it. And it gives them control over their own care.”
- “I don’t know if telehealth will be widespread, but I think it will be a shift in how people do business.”
- “There are varying levels of telehealth ... so I think it depends on the [practice’s] experience and what the office has available in terms of the type of technology they are using.”
- “There is some adaptability with some of the tools, like where you can actually listen to somebody’s heart with their smartphone up against their chest and things like that. So there are many adaptable tools that are out there already, but I don’t know how widespread their use is.”

Oct. 2019 summary: This family nurse practitioner surmises that the CMS report will not affect her Cologuard prescribing because she discusses screening alternatives with patients to help them select the test they prefer. Pfizer reps have not contacted her, but she believes the company’s reps might boost sales by marketing Cologuard much more strenuously than Exact Sciences. Her Cologuard prescriptions range from one to five per month.

3) University-based oncologist

Patient visits have decreased and companies are active in developing remote capabilities for testing. This source was not aware of the Exact Sciences telehealth program for Cologuard. He did speak to blood assay genetic testing company [Natera Inc.](#) (NTRA), which just recently [introduced](#) a new mobile phlebotomy program to get to patients who are not traveling to clinics or offices. He sees telehealth and mobile processes growing in the future as reimbursement is more firmly established and accepted.

COVID-19 Impact on Exact Sciences

- “Patient visits are down and so the use of most tests will be reduced during the pandemic.”

Impact of Online and Telemedicine on Exact Sciences

- “This should have a positive impact on the use of Cologuard. Maybe more so after restrictions are lifted and telemedicine becomes more a way of practicing medicine.”

Cologuard Use

- Did not discuss.

Telehealth

- “Cologuard is not the only company using telehealth in their process. In oncology there are a growing number of companies performing genetic testing via blood assays. Typically, blood assays are performed on site or maybe at a clinical testing lab like a Quest [Diagnostics Incorporated/DGX]. Now companies are doing mobile phlebotomy where they will travel to the patient’s house and do the blood draw. Natera is an example of a company who is now offering this option. Post cancer surgery, their test works to detect circulating tumor DNA, looking for molecular residual risk and recurrence monitoring to help determine who needs chemotherapy and who does not. It also serves as a monitoring tool for recurrence post treatment.”

This should have a positive impact on the use of Cologuard. Maybe more so after restrictions are lifted and telemedicine becomes more a way of practicing medicine.

University-based oncologist

Update: Exact Sciences Corp.'s Cologuard

- “In looking at rural and medically underserved areas, telehealth can play a big role to get medical care to patients. In congested urban areas, the COVID[-19] fear may linger and make the doctor’s office an undesirable place to visit. Public transportation may also be an obstacle. As telemedicine costs and charges become more clearly established, it offers reimbursement to doctors for what in the past was kind of free medicine and may encourage more remote medicine. Maybe not today, but for the future post COVID[-19].”

4) Gastroenterologist at an academic medical center; repeat source

Regardless of the assertion that people can send their Cologuard tests to Exact Sciences from home, the company will be substantially impacted by the COVID-19 pandemic. In his view, the company’s goal of attaining 40% of colorectal screening is overreaching. After the quarantine, telehealth services will be broadly used for patients who cannot come to the healthcare facility, and to generate revenue.

COVID-19 Impact on Exact Sciences

- “Temporarily, [COVID-19] is going to affect everyone because even though [Cologuard] is something that people send in from home, someone has to prescribe the test. And telemedicine is taking some foothold, but in-person visits to doctors are way down. All across the country, for the most part, at least in a good part of March and all of April, and, who knows, maybe part of May, elective procedures are being put on hold. We are not doing screening colonoscopies.”
- “Even with the argument that this is a test that people could send in from home, I still think [the shutdown] is going to affect Cologuard substantially.”
- “The fact is, if a Cologuard is positive, the follow-up can’t be done immediately.”
- “At the moment, we aren’t doing screening procedures.”
- “Exact Sciences is getting into [COVID-19 testing] kind of late. Yes, they have tests, but they aren’t [Abbott \[Laboratories/ABT\]](#) or [Sanofi \[SA/SNY\]](#). ... I don’t see [COVID-19 testing] as Exact Sciences’ market. I think they have to be careful not to just jump in and try to grab at everything.”
- “I think [Exact Sciences achieving] 40% of colorectal screening is very overly ambitious. ... Right now, the number of screening procedures being done anywhere has been severely limited. They will start to pick up again, but ramping up is going to take some time, as well.”

Right now, the number of screening procedures being done anywhere has been severely limited. They will start to pick up again, but ramping up is going to take some time, as well.

Gastroenterologist at an academic medical center

Impact of Online and Telemedicine on Exact Sciences

- As for whether Exact Sciences’ telehealth will promote meaningful use during the shutdown: “Probably not. I think they will get some traction out of it. I think it’s an interesting idea. In general, a lot of these types of things are being put on hold until we sort of come out of this.”
- “We have Epic. It’s a common electronic medical record. ... We’ve had it now for quite a while and once you learn how to use it and get used to it, it’s pretty easy to use.”

Cologuard Use

- “I have prescribed some Cologuard. We give patients a choice. If people ask for it, we do give them that option. I do see some patients who come in with a positive Cologuard, but it’s a very small fraction of what we do for screening. ... [Since six months ago], I have prescribed maybe two or three [Cologuard tests].”

Telehealth

- “We have telehealth services. We ramped it up fairly quickly, actually.”
- “I think, in general, a lot of telehealth will have taken hold that didn’t happen before [COVID-19]. We accelerated our process out of necessity. So there will be some of that. To what extent, I don’t think anybody knows right now.”
- “We use telehealth, for the most part, for people who have an urgent issue and they can’t get here right away. But we are also looking at the patients who ordinarily are not going to be able to come in here during this period because it’s a non-urgent situation.”
- “Yes [telehealth will be widely adopted after the pandemic]. I think there are two reasons. One is we have to see the patients who aren’t able to come in physically. So that is the first thing. The second thing is revenue. The revenue has gone down very substantially [during the pandemic]. ... If you can’t see patients, you can’t make money. There

Update: Exact Sciences Corp.'s Cologuard

are a lot of nonprofits but medicine, I hate to say it, medicine is a business, as well. So, for one, patients need to be seen. People do get ill. But it's also a revenue issue."

Miscellaneous

- "To understand the Cologuard test [patients] have to know the pros and cons, what you are doing with the blood, the test's sensitivity and specificity, and what you are really detecting. I kind of bristle a little bit at the Cologuard commercials that are on TV because they say Cologuard just uses the DNA in the stool to detect cancer. That's true, but it leaves out that it's not just a DNA test. A lot of the signal probably comes from the FIT [fecal immunochemical test] part of the test."

Oct. 2019 summary: CMS' negative cost-effectiveness analysis probably will not impact Cologuard as much as the fact that CMS pays for the test. He has ordered Cologuard twice for patients who asked for it. Cologuard will experience some stable sales growth in primary care. Patients who are likely to have blood in their stool should not undergo Cologuard testing.

Feb. 2019 summary: This gastroenterologist has not prescribed Cologuard but is not opposed to ordering the test if a patient requests it. Pfizer's marketing to PCPs and OB-GYNs will increase Cologuard prescriptions somewhat, but sales will level off. Circulating DNA is not that sensitive, so blood-based testing will require use of marker panels.

5) Gastroenterologist in private practice; repeat source

Initially, COVID-19 will cut down on use of Cologuard and colonoscopy, but Exact Sciences' percentage of total colorectal cancer screening will not change. In the future, telehealth will be advantageous for Exact Sciences and its desire to capture more market share. Before the pandemic shutdown, he found that primary care physicians were ordering a larger number of Cologuard tests for patients.

COVID-19 Impact on Exact Sciences

- "[COVID-19] is going to hurt Exact Sciences' [Cologuard] the same way it hurts routine colonoscopy. The entire economy is going to go down, Exact Sciences included."
- "Routine preventative care has been put on the back burner in this current climate. My impression would be that people are just not coming in for their routine annual visit right now. They are coming in because they have a problem that they need addressed. And one of the last things that will come back online is the routine preventative healthcare visit."
- As for achieving 40% of CRC screening: "I think that the pie is just going to shrink, and [Cologuard's] share of the pie is going to continue to be the same. I don't think that their percentage is going to increase, nor will it decrease, during this. I just think everything is going to get put on the backburner and the number of preventions is just going to go down."
- "I'm not too, too familiar with the exact nature of the Exact Sciences' [COVID-19 test], but I'm aware enough of all [COVID-19] testing around to know that's minimally impactful. ... People estimate that the demand for testing could be one billion. That's why in those states where the economy is starting to reopen ... there is no opening that is contingent on testing because there aren't enough tests. And if you tie in tests to anything that you are going to do, you will not have the supply chain of tests unless you are a big national corporation—like [HCA \[Healthcare Inc./HCA\]](#) or [Ascension \[Health\]](#) or a big hospital chain—and have your own supply chain line so that you can get your niche supplied enough to do what you want. But, even then, they are going to run out of those tests. And they are just going to abandon them is my prediction, as soon as their well of testing runs dry."

Impact of Online and Telemedicine on Exact Sciences

- "I wonder if that doctor on [Exact Sciences' telehealth] is going to tell you that a Cologuard is less than 50% accurate in finding the polyps that can turn into cancer. I'm sure that's not going to happen. But the doctor will order the test for you."
- "It's a good thing that telehealth has now become more available. It kind of shows you how the system was rigged against doing it, because all they did for telehealth to go up is drop the regulations that made it so difficult for any of us to use telehealth. And when they needed to, they just dropped the regulations and it's going to be tough for anyone to put these barriers back up now ... that providers and patients recognize the value of telehealth. We are going to continue to do telehealth as part of the way we deliver care."

Update: Exact Sciences Corp.'s Cologuard

- “[Telehealth] is particularly going to be helpful for a company like Exact Sciences, because it’s going to allow you to have direct-to-consumer advertising, which they are already do, but then you are also going to have direct-to-consumer ordering.”
- “The telehealth era is going to be a boon for Exact Sciences and their aspirations to have an increasing market share [for Cologuard]. In the future it will. In the short run, right now everybody is going to be down and flat, but when this thing turns the corner, certainly this is going to be helpful for them. They can just eliminate the middleman, the middleman being anybody with data and science, and go straight to the patient.”

Cologuard Use

- “I don’t do many Cologuard tests. Ninety-five percent of people come to see me because they want to have a colonoscopy. And there is very few who don’t want a colonoscopy and want to know the alternatives. So then, of course, the next best test is a Cologuard.”
- “I’ve done three Cologuard tests [since last October]. I’ve done zero since [the pandemic]. I’ve done zero colonoscopies since the pandemic.”
- “I think that because 40% of people don’t do preventative care, there is some market share for Cologuard, and I do appreciate, just like [Hemoccult](#), having something to offer people who don’t want to do colonoscopy. What angers me about Cologuard is their marketing, not the product. ... If you are going to tell people the accuracy rate, tell them the accuracy rate for polyps. ... What’s going to happen is that people are going to succumb to colon cancer by thinking that they are protected because they did a Cologuard.”
- “We don’t have a problem usually with people coming back for their return colonoscopy. It’s that initial colonoscopy that people are hesitant about, and I can understand it. There’s the prep, the time constraint, and the expense.”
- “Before the pandemic, there was an increased number of primary care physicians prescribing Cologuard. I get fewer colonoscopies from my routine referral doctors because they are opting for Cologuard. And these are bright, good physicians. The physicians that use Cologuard are not naïve. They are doing it because their patients come in saying, ‘I’d just rather do that.’ Nobody has the time. The patient doesn’t want to know the plusses and minuses, and the system has made it so that the doctors don’t have the time.”
- “Exact Sciences is misleading and misinforming to make themselves seem different than they are.”

Telehealth

- “We do telehealth now, and our exams are tweaked to what we can do with a visual visit. ... There is a lot of exam criteria that you can fulfill just with the visual. There are ways that we can document elements of the exam that are accurate and honest through the visual telemedicine and it gets you a level of billing that’s worth the effort to do the visit.”
- “Absolutely [telehealth will be widely adopted after the pandemic].”
- “Telehealth isn’t for everybody. It’s not what I’m going to switch over to. I think that there is an invaluable element to the patient-doctor relationship that comes from being next to each other that telehealth will never replace. However, telehealth has a pivotal niche to fill.”

Oct. 2019 summary: Cologuard is appropriate as a “second-tier test” for patients who don’t want a screening colonoscopy unless the Cologuard is positive. In his view, Exact Sciences markets Cologuard in a misleading manner that could cause consumers to view the test as equivalent to colonoscopy without having to do the prep.

The telehealth era is going to be a boon for Exact Sciences and their aspirations to have an increasing market share [for Cologuard]. In the future it will. In the short run, right now everybody is going to be down and flat, but when this thing turns the corner, certainly this is going to be helpful for them. They can just eliminate the middleman, the middleman being anybody with data and science, and go straight to the patient.

Gastroenterologist at an academic medical center

6) Practicing gastroenterologist also conducting research in CRC screening in the general public and the VA system

This nationally known gastroenterologist is working in a large academic teaching and research university-based practice in the Northwest. During the pandemic CRC screening is not a priority, so Exact Sciences’ Cologuard test volume will be negatively impacted. Following the reopening of healthcare practices, the use of Cologuard should surge. His practice,

Update: Exact Sciences Corp.'s Cologuard

and that of the entire GI division at both the academic center and at the VA, are largely closed, with screening and polyp surveillance colonoscopies down by 95%. He is looking forward to the governor's order to lift restrictions effective May 1. Patients will be able to be screened in person but will have to have been COVID-19 tested first. Both of his GI divisions will be back in business soon but at lower levels than prior to the pandemic. Both divisions are also fully trained in virtual and telemedicine consults and anticipate continuing the use of both technologies post pandemic. He sees that the use of telemedicine and virtual medicine will continue after the pandemic and will profoundly and permanently change the way he and his faculty practice.

COVID-19 Impact on Exact Sciences

- "I am aware that Exact Sciences is using an online approach to ordering Cologuard, but only because I saw it on TV. No one from Exact Sciences has contacted me about this or anything else."
- "I was not aware that they were doing COVID-19 testing, but am not surprised. Everyone is helping, between making masks and ventilators to distilleries making hand sanitizer."
- "My university has a policy that salespeople are not permitted to contact our faculty."

Impact of Online and Telemedicine on Exact Sciences

- "There is a third type of digital technology in use here ... virtual visits. This occurs through Epic and is highly controlled and documented. Telemedicine differs in that it occurs over the phone or through Zoom, FaceTime, etc., which have HIPAA concerns. The online component is merely a test kit ordering function."
- "During the pandemic, I don't see any of these technologies have a significant impact on Exact Sciences because CRC screening is just not something that is top-of-mind for the general population."
- "The use of online ordering is not a new concept here. FIT testing has been handled this way for a while. Also, you can get them through pharmacies, so this isn't a novel concept."

Cologuard Use

- "Exact Sciences will surge after the pandemic."
- "Cologuard is not frequently used by referral-type GI practices much. It is more typically used by primary care providers. I do use it, though, in my VA practice, as this is a huge population that lends itself to screening like this. I have also studied CRC screening in the VA population and have published extensively on it."

Telehealth

- "If there is a silver lining to this pandemic, it's the emergence of digital medicine. Many insurers wouldn't cover these services prior to the pandemic, but the genie is out of the bottle. This is here to stay."
- "This new online service that Exact Sciences is promoting is fine, but the results of the testing MUST be communicated to the patients' providers. I am not familiar with the exact process, but this is a must in my book."

Exact Sciences will surge after the pandemic.

Practicing gastroenterologist also conducting research in CRC screening in the general public and the VA system

2) Medical Testing Sales Channel

Exact Sciences' Cologuard is expected to experience a significant increase in use as medical practices reopen and address the backlog of CRC screenings. The ability to order Cologuard via a telehealth platform is considered one more option for patients and medical professionals but is not expected to drive significant volume. Exact Sciences' use of Epic is considered a positive. The Exact Sciences sales professional said sales of Cologuard dropped dramatically as stay-at-home orders were implemented. Over the past three weeks, however, sales have slowly started to recover. The COVID-19 environment is conducive for future sales, as a patient can be screened without having to go to a doctor's office. The use of telehealth across the medical community is expected to continue following the reopening of medical facilities.

1) Oncology sales specialist with extensive experience in selling genetic testing to oncology; repeat source

Telehealth is a great idea but is not going to help Exact Sciences right now. Patients are not going to medical offices and are even skipping scheduled chemotherapy infusions. People are thinking about the pandemic and its implications, not about their colon health. No one knows that the Cologuard telehealth program exists, as it needs to be publicized via TV or Netflix Inc. (NFLX). The integration with Epic is very positive for Cologuard.

Update: Exact Sciences Corp.'s Cologuard

COVID-19 Impact on Exact Sciences

- “[I] don’t think too many people are home thinking about colon cancer screening and doing one now during the lockdown phase of the pandemic.”
- “There will be a negative impact on number of tests, as there are very few office visits as people stay home, avoid contagion areas like a doctor’s office, and elective procedures have been cancelled.”
- “During the COVID[-19] lockdown, physician offices have been overly sensitive to companies contacting them to telepromote their products and services. If the incoming calls had to do with COVID[-19], offices were more receptive, as this addressed an immediate need. Within the oncology community, one company went over the top with their contacts with too many emails and calls and the result is they have been banned from all oncology offices.”
- “Patients are not showing up for their appointments and in oncology we hear about patients who will not come to offices for their regularly scheduled chemotherapy infusions.”

Impact of Online and Telemedicine on Exact Sciences

- “Telehealth for colon cancer testing driving use is very doubtful. I do not think patients are going to the Cologuard website and ordering their own test. Patients do not know the telehealth capacity exists—no one has told them. There is no advertising, no messaging to let patients know this exists.”
- “Exact Sciences need to publicize their telehealth platform to make it a driver of growth. What are people doing while in shutdown? Watching Netflix is a big one. They should work with Netflix to get opinion leader messages about this as a patient health message. [Dr. Zuri Murrell](#) at Cedar Sinai does public health messages on TV to get to know your colon health. Exact [Sciences] needs to be thinking like that.”

Cologuard Use

- “The tie-in with Cologuard and Epic is important and will help Cologuard grow faster. This is a great move.”
- “The use of Cologuard is not strong in the specialty offices.”

Telehealth

- “Telehealth is interesting, but I doubt it is important at this time to help with CRC testing. After offices reopen, and if it is advertised so people know it exists, then it could help to expand Cologuard’s use.”

The tie-in with Cologuard and Epic is important and will help Cologuard grow faster. This is a great move.

Oncology sales specialist with extensive experience in selling genetic testing to oncology

Oct. 19, 2019 summary: The CMS cost-effectiveness study will have little immediate impact on the use of Cologuard. This source perceives the inherent weakness of the test is that it is not performed in the office and has lower than reported compliance. The 45- to 49-year-old label expansion is not a medical revelation but will drive growth. One area for concern is with the Genomic Health acquisition and their sales force. Their breast and prostate cancer genetic tests are market leaders, but there is turmoil in the sales force, as they are losing tenured reps to the competition and replacing them with lower compensated and less experienced reps without the same levels of office access, due to their lack of seniority. This source believes Genomic Health to be critical to the future of Exact Sciences.

Feb. 15, 2019 summary: The addition of the Pfizer sales force will increase Cologuard usage but will be limited, as physicians need better solutions to ensure patient compliance. Many patients cannot get over the emotional barriers of testing to allow the scientific benefits to prevail. Without a change in marketing to patients and PCPs, Cologuard will not realize its

2) Salesperson for Exact Sciences; repeat source

This Exact Sciences sales professional witnessed a dramatic drop in Cologuard sales as COVID-19 resulted in office closures but, for the past three weeks, sales are slowly recovering. This source does not have high expectations for the telehealth program as a major revenue driver but sees it as another option that Exact Sciences can offer the clinician and the patient. Overall, the COVID-19 pandemic environment is very favorable for the use of Cologuard for the foreseeable future.

COVID-19 Impact on Exact Sciences

- “Things are changing weekly for Exact Sciences and sales of Cologuard is related to the closing of offices.”

Update: Exact Sciences Corp.'s Cologuard

- “Exact Sciences did furlough some people—the press release said 2%—and these were headquarters people. I don’t believe any salespeople were furloughed.”

Impact of Online and Telemedicine on Exact Sciences

- “The telehealth program doesn’t seem to be an intention strategy to expand usage but just an option. My expectation was never that this was going to be a big driver, but a great option for some patients to do CRC screening from home.”

Cologuard Use

- “As soon as a state was ‘closed,’ the drop-off in sales was dramatic. You could see it by state and by healthcare system.”
- “Over the past three weeks, Cologuard usage has begun to improve. A slow recovery over these past three weeks.”
- “Lots of patients have kits at home and have not used them. We’re having follow-up calls to encourage their use and get these patients screened and increase kit usage.”
- “The environment we are in is really very favorable to Cologuard. Patients are scared to go to doctors’ offices or hospitals, and this is a great option. There is a growing backlog of patients who need screening for CRC and this is very favorable for Cologuard.”

“The environment we are in is really very favorable to Cologuard. Patients are scared to go to doctors’ offices or hospitals, and this is a great option. There is a growing backlog of patients who need screening for CRC and this is very favorable for Cologuard.”

Salesperson for Exact Sciences

Telehealth

- “Some health systems are pushing their patients to the telehealth platforms they are putting in place as an active strategy during this pandemic environment.”

Oct. 2019 summary: This regional sales executive has not had any customers inquire about the CMS study nor heard of pushback from systems or payers relative to the CMS cost-effectiveness study. There are many assumptions in the trial that make it flawed and not real world. In the short term, some prescribers and systems might get confused and raise questions, but, in the long term, this study will have little effect. Payer coverage is a strength and high growth in sales will continue for the foreseeable future. The expanded label will grow sales and gain payer support. The Genomic Health acquisition is exciting and important to the future of Exact Sciences.

3) Account executive for a major genetic testing company

There will be immediate increases in Cologuard volume as offices reopen and address the pressing needs of their practices and patients. The gains will be temporary, though, as the backlog is addressed, since Cologuard cannot truly replace a colonoscopy. The use of telehealth will continue as practices reopen to lower the risk of patients coming into offices.

COVID-19 Impact on Exact Sciences

- “There will be gains immediately after offices reopen, but the gains will be short-lived, as there is no substitute for colonoscopy”

Impact of Online and Telemedicine on Exact Sciences

- “Short-lived.”

Cologuard Use

- “Cologuard will enjoy a short-term success when healthcare professionals are reopening their practices and addressing patient needs that went unaddressed for several months. I think the gains will be short-lived, as Cologuard is not a true substitute for a colonoscopy. Colonoscopy is the best option.”

Telehealth

- “We are using different virtual options for testing with my company. All options allow patients to speak with genetic counselors and do at-home collections. I do believe this process will last so patients can call from their home and not have to go to the office or hospital and put themselves at risk.”

Update: Exact Sciences Corp.'s Cologuard

3) Industry Specialists

Exact Sciences is poised for a strong recovery following the COVID-19-related shutdown of medical practices, which has led to declines in Cologuard test volume. Exact Sciences' online ordering and telehealth program will help increase test volume, as some patients will fear going to medical facilities and physician's practices operate with new safety and patient protection procedures that will stress more efficient treatment methods. The use of telemedicine is expected expand post COVID-19 to assist with anticipated patient backlogs and because insurance companies are now more willing to reimburse for its use.

1) Executive at a nonprofit healthcare organization; repeat source

Exact Sciences' telehealth program will boost Cologuard usage immensely, given that they do considerable direct-to-consumer marketing and people have trepidation about going to a healthcare facility during the pandemic. The source predicts that the pandemic will help Exact Sciences attain its 40% market share goal for Cologuard more quickly in the long term. Screening delays could lead to patients' later-stage colon cancer advancing to the next stage.

Disclosure: The nonprofit organization receives sponsorship and support from Exact Sciences for education around colon cancer screening.

COVID-19 Impact on Exact Sciences

- "I think there are two sides to the coin. One side is very positive because if people potentially need a screening and know they can't go into the endoscopy suites, they may look at a first line screening with either FIT or Cologuard. So I think that, especially because Exact Sciences has a navigation program, that could increase the number of Cologuard tests."
- "On the negative side, it may cause a little bit of fear and anxiety if you get a Cologuard test and it comes back positive, because you may have to wait longer than normal to get a follow-up colonoscopy."
- "We want to actually be promoting these non-invasive tests right now because if we don't we are going to see many more late-stage colorectal cancers come through the pipes."
- "The [COVID-19 pandemic shutdown] is going to be devastating to a number of people who get diagnosed with later-stage colorectal cancer. Let's say they were supposed to have their follow-up in January and they have to wait until September. That can make the difference between stage 2 and stage 3, or stage 3 and stage 4."
- "I think [Exact Sciences' involvement in COVID-19 testing] would only be a positive thing."
- "I definitely think that [the pandemic] will have slowed down the timeline of when Exact Sciences would get to that 40% [of CRC screening]. ... It could speed it up, though. If you think about it, right now, if people can't leave their homes and we come up with these coalitions that allow people to get screened more with FIT tests and with Cologuard, it would increase [Exact Sciences'] market share faster."

Impact of Online and Telemedicine on Exact Sciences

- "Absolutely, [Exact Sciences' telehealth program will drive meaningful use of Cologuard during the shutdown]."
- "We are seeing the use of telemedicine going from, like, the Dark Ages to 2050 in the course of two months. ... And I think the technology and the navigation program that Exact Sciences has and Cologuard has will only help. Our society in these two months that we have been in this [pandemic shutdown] has gone from barely using telemedicine to everybody using it. Exact Sciences was already kind of leading the way in navigation, both from a telemedicine perspective and from a phone perspective."
- "I think Exact Sciences' telehealth will help increase their [Cologuard] sales tremendously because of the fact that Exact Sciences does a lot of direct-to-consumer marketing and patients at this time are afraid to go to the hospital,

I would say telehealth [before and after the shutdown] will only help Exact Sciences reach their 40% market share faster. I do, in fact, think this pandemic, over the long term, will help them get there quicker. I think over the short term, maybe not, but over the long term, yes.

Executive at a nonprofit healthcare organization

Update: Exact Sciences Corp.'s Cologuard

let alone what the guidance or guidelines are saying, so I think it will only increase the number of people who are getting Cologuard.”

- “When I meet with people ... everybody asks me about [Exact Sciences’] dancing box commercial. It’s their main commercial for Cologuard. So I do know there is a large awareness of Cologuard screening. I don’t know the percentage of people who know about the telemedicine program.”
- “I would say telehealth [before and after the shutdown] will only help Exact Sciences reach their 40% market share faster. I do, in fact, think this pandemic, over the long term, will help them get there quicker. I think over the short term, maybe not, but over the long term, yes.”

Cologuard Use

- Did not have any specific knowledge regarding the use of Cologuard.

Telehealth

- “Most patients, including cancer patients and people looking for preventive screening, are utilizing telehealth.”
- “Yes, absolutely [telehealth will be widely adopted] after the pandemic. People really get used to being at home. I think people for a while are going to be afraid to go out and I think, even after people are allowed to go out, if they see an option like [Cologuard] to be able to stay home, they are going to do it.”

Oct. 2019 summary: Cologuard and other non-invasive tests are certainly important as a first step in screening. The response to the Genomic Health acquisition has been quite affirmative. Genomic Health’s Oncotype Dx is used to establish that a patient with stage 2 colorectal cancer needs chemotherapy. Cologuard has an enormous runway.

2) PBM Executive; repeat source

This source believes Cologuard will have much more opportunity for use and growth in the post-COVID-19 world but with that will come increased scrutiny on their sensitivity and economy. Service providers will be downsizing in-office staff, with fewer personnel and more remote service options. This will give Cologuard a great opportunity. Healthcare providers will have a backlog of patient needs to handle and Cologuard and non-office services will be leaned on. Telemedicine and remote procedures will enjoy increasing insurance coverage and, consequently, increased use.

COVID-19 Impact on Exact Sciences

- “People are staying home due to the pandemic so wherever there are technologies and innovation that save money and personal risk, there will be high interest by healthcare professionals, payers, patients. Technology can put patients at increased ease. This is especially true for the older patients.”

Impact of Online and Telemedicine on Exact Sciences

- “I think post-COVID[-19] reopening there will be less staff in healthcare provider organizations—a combination of less staff in the office place and more working remotely. I believe this will be the new model and products and services that facilitate this will enjoy growth. Insurance will increasingly cover these services that may not have been covered in the past.”
- “Benefits coverage and design will be reviewed, as this new means will be more prevalent. They should get better coverage.”

Cologuard Use

- “Cologuard and colonoscopies will be decreased in usage during the lockdown. I think there is more noise about the risk of injury from colonoscopies and, therefore, the option of Cologuard is gaining favor.”
- “Regarding the 40% target of Cologuard, I don’t think the post-COVID[-19] world will necessarily help them reach their goal. Insurance coverage will be considering more new technologies and options. More companies and insurance carriers will be conducting their ‘due diligence’ on these options. There will be more interest in emerging options, but with this comes more scrutiny on sensitivity, selectivity, and economy.”

Telehealth

- “Telehealth will be important in handling the backlog of services patients need that are building during the coronavirus. A good option.”

Cologuard and colonoscopies will be decreased in usage during the lockdown. I think there is more noise about the risk of injury from colonoscopies and, therefore, the option of Cologuard is gaining favor.

PBM Executive

Update: Exact Sciences Corp.'s Cologuard

- “My insurance carrier reached out to me as a covered life to inform me they are covering telehealth measures and that it is an option I can now choose.”

Oct. 2019 summary: This source has not heard anything of the CMS cost-effectiveness trial from his clients and does not believe it will have implications in the short term. The source believes that Cologuard’s growth should remain strong until more blood assays compete with Cologuard.

Secondary Sources

These two secondary sources focused on the dramatic decline in medical testing that is creating a large backlog and Cologuard as a potential solution.

April 14 U.S. News [article](#)

Telemedicine and Cologuard are highlighted as tools for maintaining preventive healthcare during the pandemic.

- “Venues and methods may have shifted due to COVID-19, but it’s still crucial that patients stay on top of other critical health issues.”
- “BEFORE THE coronavirus dominated the lives of patients and doctors alike, many primary care physicians focused on preventive health with their patients, including through cancer screenings and informing them about heart disease. Yet in order to reduce the spread of COVID-19, as well as funnel resources toward combating this global pandemic, many preventive care visits and procedures are being put on hold.”
- “It isn’t clear how long the pandemic will last, but some suggest the virus could prove dangerous for another year or longer, and there is no question it remains our most imminent threat. This has led to primary care physicians and specialists being redeployed to emergency departments and ICUs to help meet increasing demand, postponing preventive care visits and important procedures. Yet other medical ailments cannot be put on hold indefinitely, and patients cannot ignore their health. Strategies must be developed to assist patients and physicians in navigating healthcare in this new landscape.”
- “Virtual care in the form of telephone and video visits has allowed many physicians to continue treating patients while still adhering to social distancing recommendations. These types of visits are very effective for evaluating and counseling patients on a number of medical issues, but have limitations when it comes to preventive measures such as cancer screenings.”
- “In some instances, other options for screening exist or are being developed. Cologuard – an at-home, stool-based test – provides an effective colorectal cancer screening for some individuals. While colonoscopies remain the standard, Cologuard can offer a way for patients to stay on track with recommended screenings while remaining at home. If a Cologuard test comes back positive, a diagnostic colonoscopy can be scheduled in the future.”

April 28 MSN [article](#)

Medical testing has declined significantly since the implementation of COVID-19-related stay-at-home guidelines. The decline will result in a four- to six-month backlog for each month tests are delayed. The lack of preventive screening will lead to serious medical problems that will be expensive to care for.

- “Routine medical tests critical for detecting and monitoring cancer and other conditions plummeted in the United States since mid-March, as the coronavirus spread and public officials urged residents to stay home, according to a new report by Komodo Health.”
- “Millions of patients postponed tests considered crucial for detecting early signs of disease, monitoring its progression and improving patient outcomes, according to Komodo, which has one of the nation’s largest medical claims data bases and provided its new findings exclusively to Reuters.”
- “‘We’re seeing a tremendous impact on preventative care, as well as on chronic conditions with massive implications for the healthcare system,’ said Komodo Health Chief Executive Dr. Arif Nathoo. ‘It speaks volumes to just how much COVID is impacting everyone’s health and wellness.’”
- “The growing backlog has created new challenges for hospitals, physicians and clinics. Some practices estimate a four- to six-month delay for each month of lockdown that prevents routine visits and screening.”

Update: Exact Sciences Corp.'s Cologuard

- “Diagnostic screenings may not be as lucrative for hospitals and physicians as elective procedures, like knee replacements and cataract surgeries, but they play a crucial role in detecting problems that can lead to more expansive care, said Mallory Caldwell, principal at Ernest & Young.”
- “The sheer volume of routine office visits and diagnostic exams also sustains many medical practices, especially in low-income communities and rural areas that were already struggling before the outbreak. Last year, 19 rural hospitals shuttered, the highest spike of closures in a decade.”

Additional research by Karen Lusky, James Boland, and Bruce Wicks.

The Author(s) of this research report certify that the information gathered and presented in this report was obtained in accordance with Blueshift Research's compliance protocols as outlined in the company handbook. All Blueshift reporters identified themselves as reporters/researchers from Blueshift Research and articulated the purpose of the research. To the best of our knowledge and efforts, Blueshift confirmed that the underlying source(s) lawfully obtained the information shared with Blueshift and were entitled to provide such information to Blueshift without breaching a duty to another party. The data in this report has undergone review from Blueshift Research's Compliance Officer and has been approved for distribution to Blueshift Research's clients.

© 2020 Blueshift Research LLC. All rights reserved. This transmission was produced for the exclusive use of Blueshift Research LLC, and may not be reproduced or relied upon, in whole or in part, without Blueshift's written consent. The information herein is not intended to be a complete analysis of every material fact in respect to any company or industry discussed. Blueshift Research is a trademark owned by Blueshift Research LLC.