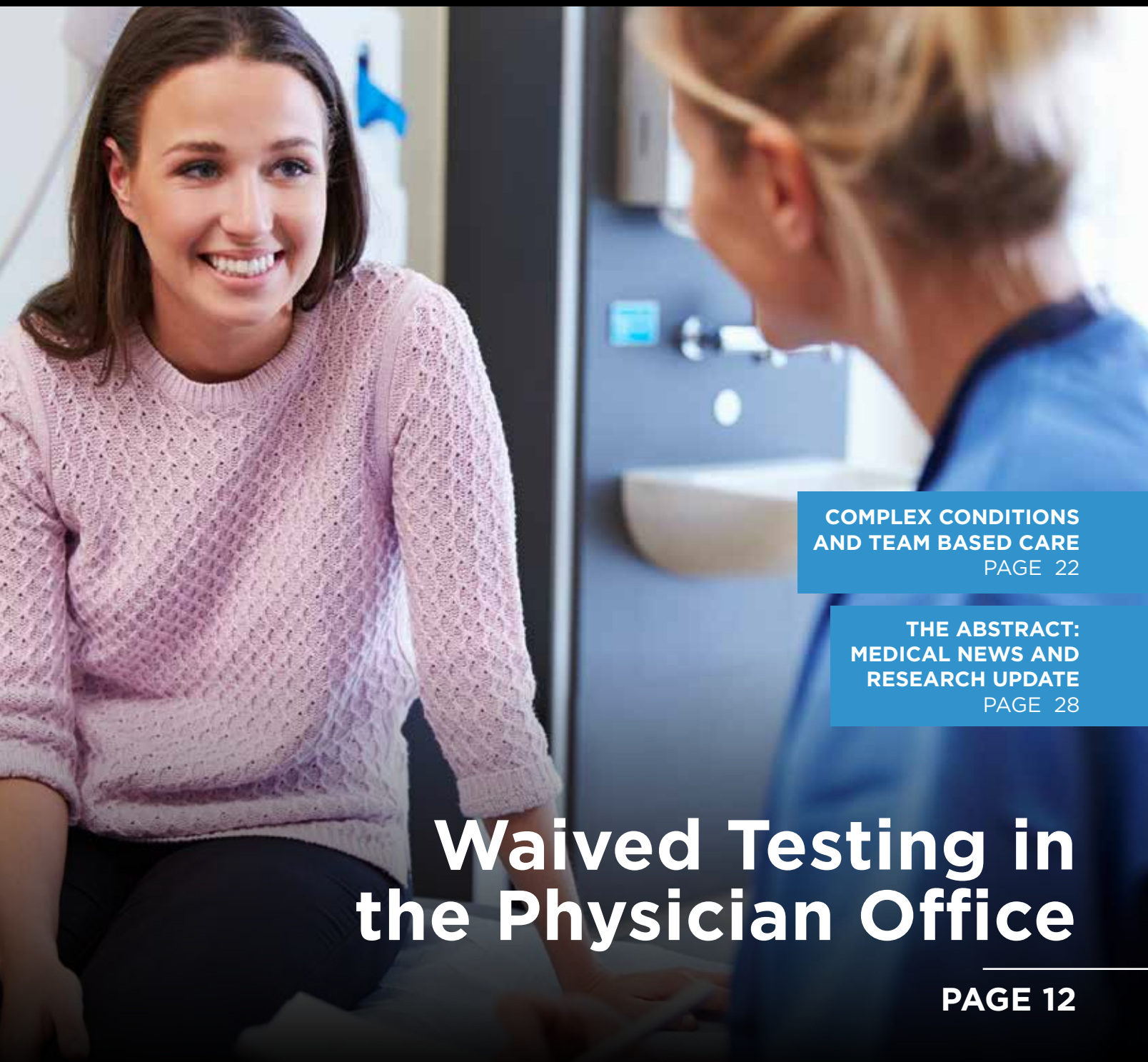
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Physicians office Resource

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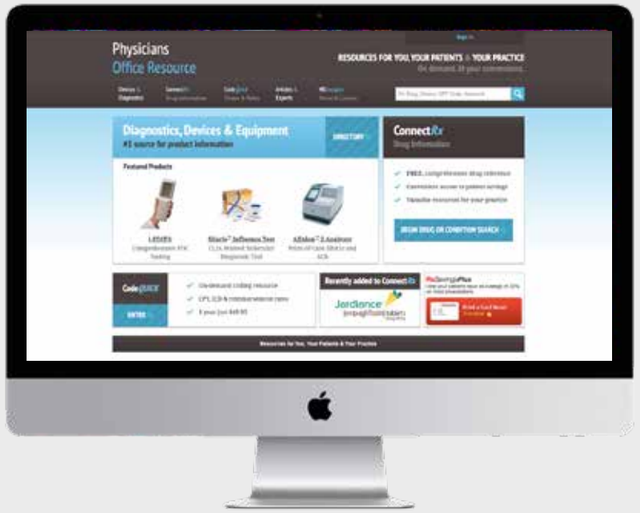


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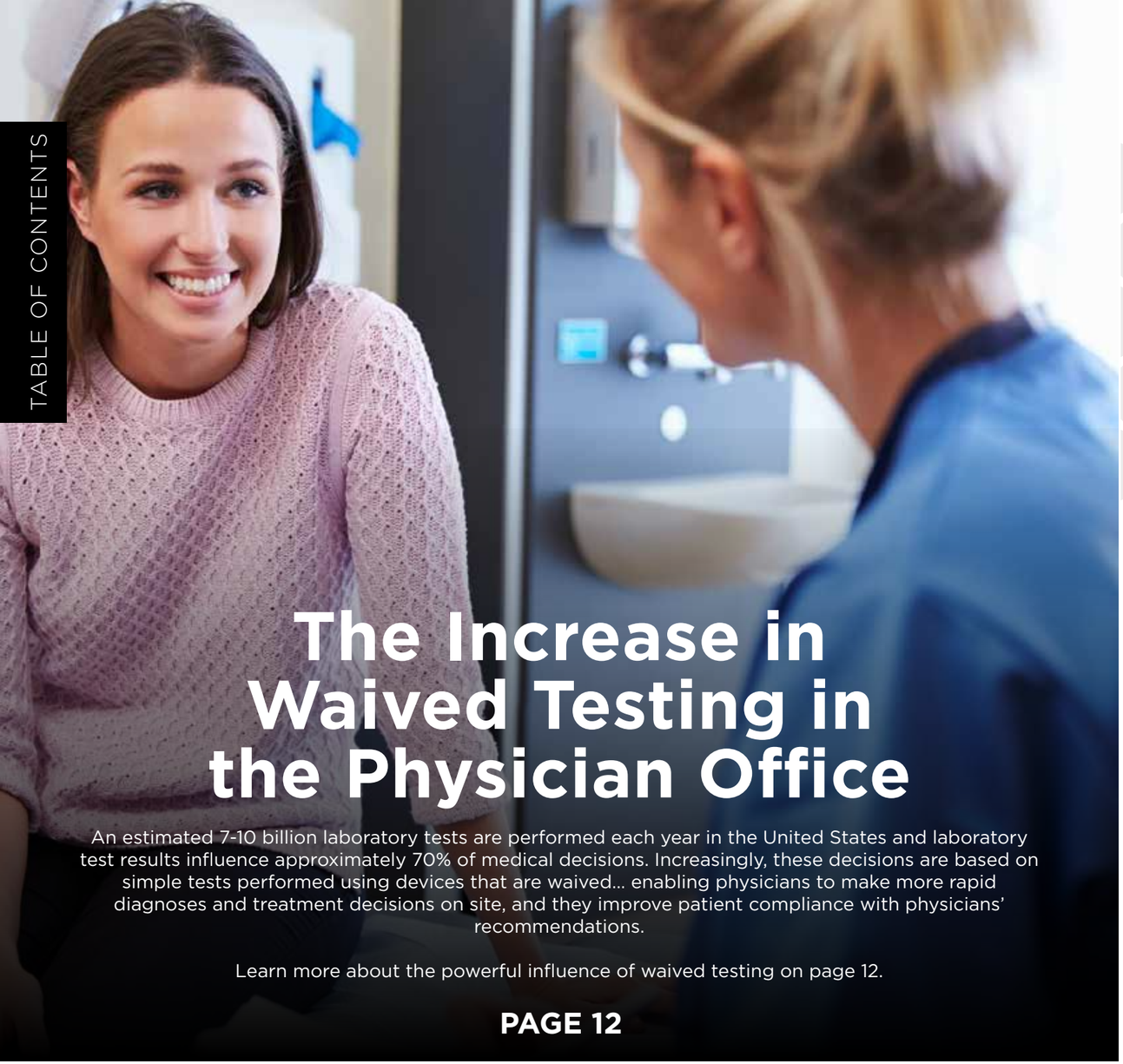
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The Increase in Waived Testing in the Physician Office

An estimated 7-10 billion laboratory tests are performed each year in the United States and laboratory test results influence approximately 70% of medical decisions. Increasingly, these decisions are based on simple tests performed using devices that are waived... enabling physicians to make more rapid diagnoses and treatment decisions on site, and they improve patient compliance with physicians' recommendations.

Learn more about the powerful influence of waived testing on page 12.

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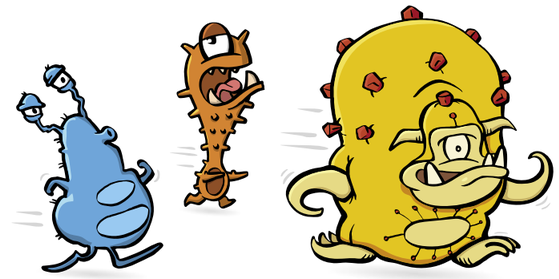
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If health care had a definitive "face," the primary care physician would likely occupy the position. The primary care physician is often a patient's first contact with recovery and in turn, plays a crucial role in public health care: making the initial diagnosis.

28

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2. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration.

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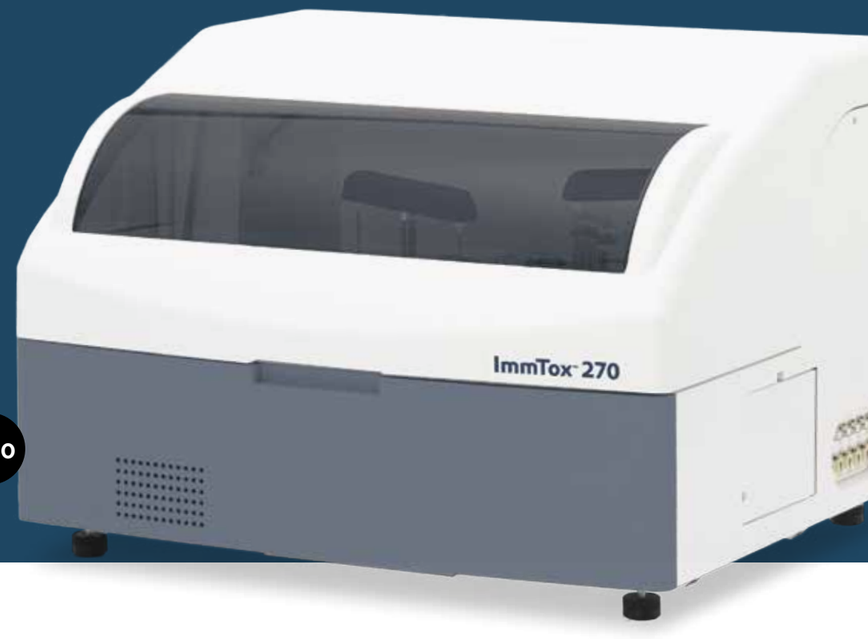
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Point-of-Care Testing

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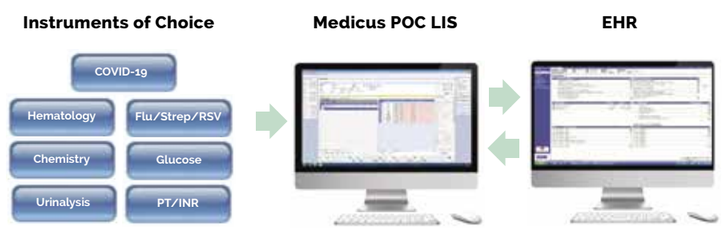
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THE INCREASE IN WAIVED TESTING IN THE PHYSICIAN OFFICE

BY IRWIN Z. ROTHENBERG, MBA, MS, M.T. (ASCP),
TECHNICAL WRITER/QUALITY ADVISOR, COLA RESOURCES, INC.

Introduction

Laboratory testing plays a critical role in health assessment, treatment, monitoring, and ultimately, the public's health. Test results contribute to diagnosis and prognosis of disease, the monitoring of treatment and health status, and population screening for disease. An estimated 7-10 billion laboratory tests are performed each year in the United States and laboratory test results influence approximately 70% of medical decisions. Increasingly, these decisions are based on simple tests performed using devices that are "waived" from most federal oversight requirements, and are thus designated as waived tests.

When these waived laboratory tests are performed at or near the site of patient care - such as in an emergency room or urgent care clinic, or at patient's bedside - they fall under the definition of Point of Care Testing (POCT). Physician office laboratory testing also is included under the definition of POCT when these tests are performed, and the results are provided to the physician, while the patient is still present and diagnostic and treatment decisions can then be made utilizing this information.

The rapid growth of POCT testing is a prime driver for the increase in waived testing at physician office laboratories, and is a direct result of the convergence of several trends that are already impacting POL operations:

- Technological advances that bring higher quality waived testing closer to the patient,
- The decentralization of laboratory services, so that POLs can now perform testing previously confined to core laboratories
- The Increased number and variety of tests classified as CLIA-Waived, and available to POLs
- Growth of Drugs of Abuse/Pain Management Clinics performing drug testing in-house

Bringing Laboratory Services Closer to the Patient

The increased number of waived tests now available for physician office laboratory testing eliminates the need for trips to and from a central core laboratory (and specimen collection sites that are run by laboratories). These tests enable physicians to make more rapid diagnoses and treatment decisions on site, and they improve patient compliance with physicians' recommendations.

Garnering information on site often allows immediate treatment, which avoids requiring the patient to make multiple trips to the physician office and pharmacy, saving time for both the patient and the clinician. Accurate diagnostic information at the point-of-care saves critical medical resources and improves both patient and clinician satisfaction. In light of the role of waived testing in the healthcare delivery system and their overall benefits, the availability of and timely access to these technologies will continue to be important to meet the needs of patients and clinicians for rapid and reliable testing.

New Tests/Instruments = Increased Demand = Additional New Tests/Instruments

This demand for point-of-care capability has spurred the development of smaller, faster, and easier-to- use tests that are more sophisticated in design than tests traditionally found in smaller office laboratories.

Since the inception of CLIA 88 and the concept of waived testing, technological advances that simplified test processes and increased reliability of test results, has led to a dramatic increase in the number of approved waived tests from 9 to 119; and the number of test systems to over 1600.

Some of the waived now tests performed in the physician office include streptococcus testing, HIV testing, INR (coag-

ulation) testing for Coumadin, and pregnancy testing. The ability to immediately treat the patient for these and other conditions, without having to send a sample to a central laboratory, can be critical to the patient's well-being. As an example, a positive test for strep can allow the clinician to immediately prescribe antibiotics, catching an infection before it becomes severe, with potential health consequences (or ruling out strep and avoiding unnecessary use of antibiotics).

According to research, POC testing is growing faster than any other segment of the diagnostic industry with an average growth rate of 14% a year. Of this, CLIA- waived is the fastest-growing segment of this market. The number of Waived labs had increased from 20% in 1992 to 75% of the more than 270,000 CLIA laboratories in 2021. Of these waived labs, 67% were POL's.

Pain Management / "Drugs of Abuse" Testing

Pain management is one of the fastest-growing reasons for waived testing. With an increasing number of internists and anesthesiologists opening pain clinics, and primary care and family practice physicians opting to treat patient pain in house instead of referring out to specialists, the pain management opportunity is ever increasing. Pharmaceutical companies are encouraging physicians to perform drug tests to monitor prescription compliance and aid in risk management.

The number of free-standing and university-based clinics in the U.S. alone has increased from just 500 in 1998 to 2,000 in 2008. Each of those clinics on average treats approximately 400 chronic pain patients per month. Over 70% of these patients are prescribed some form of opiate medication. Deaths caused by overdose of prescriptions drugs also are on the rise and, as a result, one of the prescribing guidelines, indicated by the National Pain Foundation, is to evaluate patients for the risk of abuse before starting opioid therapy. Drug testing helps the doctor in evaluating the patient's drug history as well as aids them in avoiding or minimizing a possible reaction to other medications or narcotics. Physicians, not necessarily skilled in recognizing the signs for drug abuse or addiction and wanting to exercise caution, are also being proactive and instituting drug testing as a regular part of their patient evaluation.

The tests are even used to monitor patients and their adherence to a pain management protocol of narcotics prescribed. Testing is sometimes used to determine if in fact the patient is taking their prescribed medications.

What does all this mean for the physician office laboratory?

1. The continued expansion of testing classified as waived, including those involved with drugs of abuse, infectious disease screening, and chronic disease management, provides the opportunity for greater point-of-care testing by physician office laboratories, while the patient is present, facilitating immediate medical decisions, the initiation of treatment, and continued monitoring.

2. The growing utilization of waived testing in a physician office setting brings great benefits for patient care, but it also brings great responsibility to ensure that the results obtained are of the highest quality to realize these potential benefits. These responsibilities include ensuring adequate personnel training and competency assessment; performance of required quality control, maintenance, and calibrations of the instruments used; proper specimen collection, handling and labeling, and documentation of test results. This requires maintaining adequate oversight and accountability.

3. Efficient, quality-run physician office laboratories, able to provide a larger array of on-site testing that provides faster results, diagnosis and treatment decisions support the goals of patient-centered laboratory service.

Endnotes

1 COLA White Paper: "Federal Government Questions Quality In Waived Testing. The Hard Facts and What Can Laboratories Do Now?" 2013. http://www.cola.org/docs/waived/whitepaper.pdf

2 Waived Testing and patient Safety: Future Trends. COLA Insights January/February 2015. Irwin Rothenberg

3 CMS.gov. Certificate of Waiver Laboratory Project / Requirements of waived Tests 2014. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html

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*2016 Proficiency Testing Results, American Proficiency Institute, www.api-pt.com [*Piccolo Xpress*]. See cartridge information at www.pointofcare.abbott [*i-STAT*].

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***Piccolo Xpress* Part No:** 07P05-50 *Piccolo Xpress* with 3YR Serv, 07P05-51 *Piccolo Xpress* with 5YR Serv

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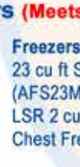
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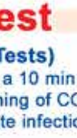
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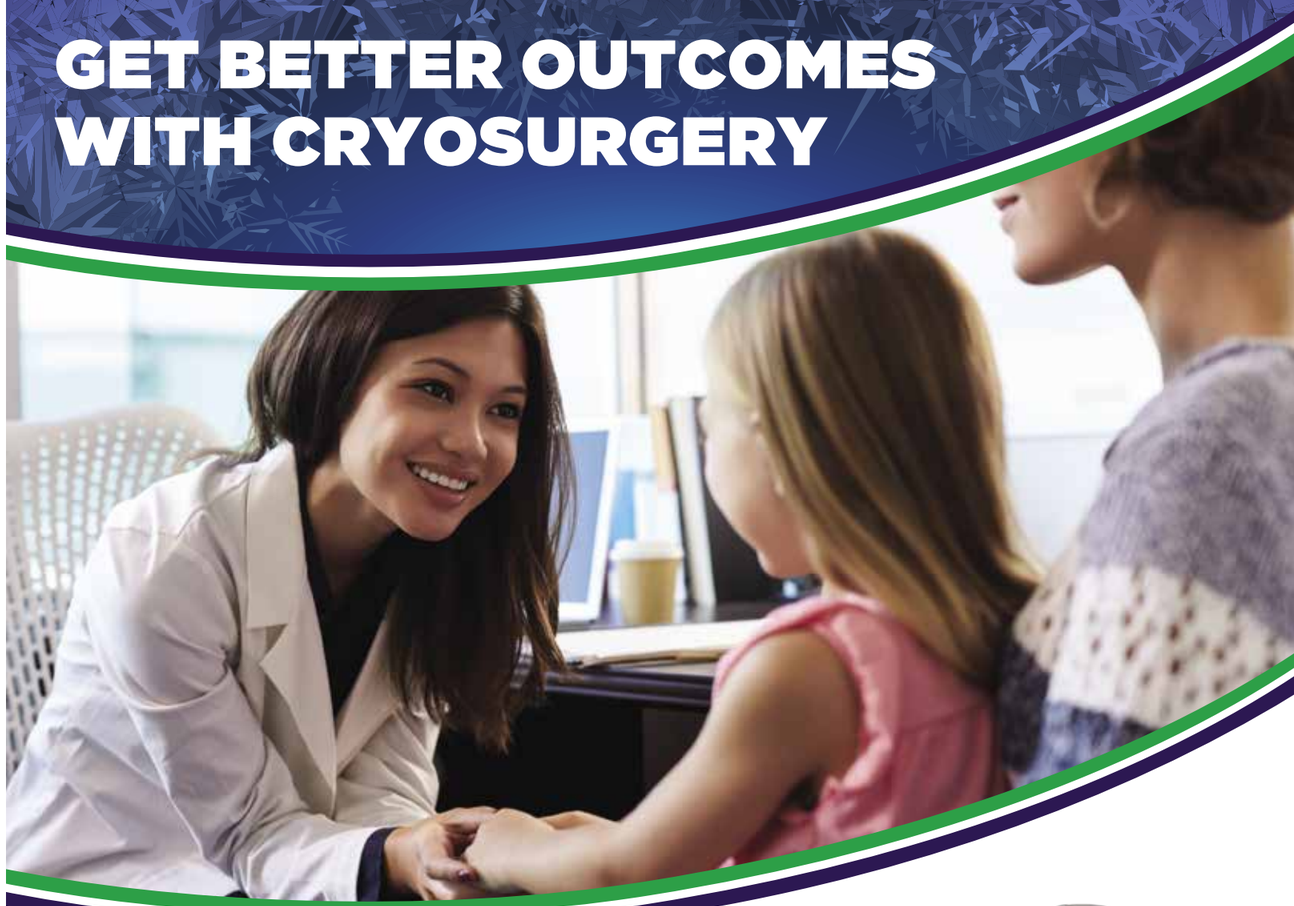
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FEATURE

Complex Conditions and Team Based Care

BY DYLAN CHADWICK



If health care had a definitive "face," the primary care physician would likely occupy the position. The primary care physician is often a patient's first contact with recovery and in turn, plays a crucial role in public health care: making the initial diagnosis.

Primary care physicians see a staggering variety of patients and conditions on a day-to-day basis. Many of these conditions are treatable within one office visit, but occasionally they're more severe. When patient conditions are determined to be more complicated, or specialized, primary care physicians can refer them to specialists, who can address these patients in a more specific manner, drawing on their own experience of a given school of medicine. Patients then convene with specialists regularly to monitor their condition and develop a treatment plan. This is the traditional (and highly paraphrased) pattern for how most patient diagnoses work. However, recent data from the Robert Graham Center for Policy Studies in Family Medicine and Primary Care indicates that this paradigm is rapidly shifting, and that more and more patients, particularly those with complicated and chronic health conditions, are seeking the advice and care of their primary care doctors than they are with specialists and sub-specialists. The development becomes increasingly more interesting when examined in the current health care climate that seems constantly faced with threats of imminent physician deficits, and statistics the number of medical students entering primary care in flux.

Just How Much?

A summary of the aforementioned research, published in the Journal of the American Board of Family Medicine illustrates these shifts. Led by Manisha Sharma, MD, a visiting scholar at the Graham Center, and a research team, the study (entitled "Patients with High Cost Chronic Conditions Rely Heavily on Primary Care physicians") examined outpatient physician in an effort to determine the frequency of primary care visits versus specialist visits. Their data was culled from a National Ambulatory Medical Care Survey for care, provided for each of the 14 high-cost chronic conditions listed in the Centers for Medicare and Medicaid Services Chronic Conditions Dashboard.
Their research indicates that 86 percent of asthma visits occurred in the primary care physician offices, verses 14 percent which occurred in sub-specialist offices, as well as 84 percent of visits for chronic obstructive pulmonary disease which occurred in primary care physician offices, versus 15 percent in sub-specialist offices. Both conditions represent a substantial portion of health conditions that all physicians must treat, with CDC and American Lung Association figures attributing $56 billion in medical costs for the former and $49.9 billion for the latter.

"These data demonstrate how much patients depend on primary care physician to take care of these complex and chronic conditions," says Andrew Bazemore, MD, MPH, director of the Graham Center. "Many of these patients have multiple chronic conditions, so a physician with expertise in the whole person and the broad range of medical diagnoses is instrumental to ensuring that all their health needs are met."

This data has led some team members to push for a semantic distinction for those in "primary care" suggesting that the name "Primary Care Physician" fails to account for the entirety of their position. Since an increasing amount of the country's health burden continually falls on these physicians, some suggest that the name "complex care physicians" is more accurate.

What's in a Name?

But why bother with this kind of distinction? Does it truly matter? In terms of public health, it doesn't, but the suggestion does indicate a changing landscape for primary care medicine generally. Essentially, the data suggests that the role and influence of, as well as the dependence on, primary care physicians has been expanding, and it may be time for other members of the health care equation to shift as well.

Chronic health conditions are defined as those which result in long-lasting effects. Generally speaking, diseases become "chronic" when their effects last for longer than three months. After a diagnosis from a primary care physician, patients with chronic conditions often learn about the necessary lifestyle decisions and habits they must make, to properly deal with the condition. The subsequent result (and truthfully, the goal) of these visits often becomes a long-lasting relationship between the physician and patient which involves multiple visits, check-ups and progress monitoring.

Complex, or complicated conditions are those which arise from various interactions between inherited traits ("nature") and environmental factors ("nurture"). One of the most immediate and identifiable examples of a complex condition would be cancer in its various forms. "More and more primary care physicians must not only identify medical needs of patients with chronic conditions, but they also must identify, coordinate, facilitate and manage issues surrounding and shaping these conditions such as lifestyle behaviors, food access, safety, and social, environmental and economic conditions," says Sharma. "That's not simple, primary care medicine. That's complex care medicine."

Indeed, when it comes to complex and chronic patient conditions, primary care physicians wear a host of differing "hats" to provide total and lasting healthcare to their patients.

Team-Based Care

The specific and long-lasting nature of chronic and complex conditions, and the fact that primary care physicians are likely to be the physicians shouldering these burdens, highlight a push for more "team-based" care. Data from the study hypothesizes that, on average, primary care physicians would need 10.6 hours per working day to adequately care for patients with multiple chronic conditions, a serious time investment!

In these particular cases, patients would benefit from a team or network of care providers who can collectively help them execute treatment plans and coordinate care strategies care with other providers and community resources. This would make great strides to delegate care and alleviate some of the burden from primary care physicians.

A Becker's Hospital Review article entitled The Affordable Care Act and Physicians: A Prescription for Change describes team-based care as a method for physician "capacity expansion." It's a re-interpretation, an evolution of the health care delivery model that employs the use of information technology and a re-design of the care delivery structure to account for a "team" of resources which care for patients. They suggest that medical practices establish procedures and policies geared towards each team member practicing to the highest level of their individual license, granting multiple team members, through the appropriate platform, access to information to best suit the needs of the patient.

The article also suggests that physicians adopt the best technology for the best purpose. As an example, primary care physicians, and other members of the care team, can utilize frequent communication with patients through various online platforms, including Email. Chronic and complex conditions often necessitate long term communication, and an email can be just as beneficial for an entire office visit, and it's cheaper. Furthermore, physicians can invest more time in disseminating non face-to-face "touch points" with patients like telemedicine, informational web pages and mobile technology.

A move towards a more "role-based" expectation model for staff members could lend greater responsibility to each team member. It will also involve some level of coordination and communication among team members, significant training on leadership skills and a structure put in place for team management.

Some Set-backs

Team-based care isn't without its own share of sticking points. For one, expanding the flow of patient information always introduces the risk of privacy breaches, especially when health information is being shared along a chain of command. It goes without saying that any changes made to patient information command would involve special protocol and security checks.

It can also affect payments and reimbursements. When physicians place a greater emphasis on disseminating health care information, they're taking their in-office services into an arena that's often not covered by Medicare or other insurance providers.

Finally, when the process of distributing health care is "shared" among a variety of professionals, patients may experience an extended time between their need for care and their actual treatment.

The Next Chapter

There's certainly no "magic bullet" scenario here. However, in an era where health care reform practically forces some elements of team-based care, and when primary care physicians are finding more and more of their time and services for complicated conditions being demanded, the need for delegation becomes increasingly crucial.

"Value based" health care, health care that seeks to improve the population's health while also increasing patient and physician satisfaction is a model that requires a fair amount of work, planning and re-structuring. It involves engaging physicians in assessing their health models and incentives, creating the most efficient platform that provides the best access to data and a "holistic" view of patients that extends beyond the office.

No one can definitely say where exactly reform will take health care, but the need for new care models may become apparent. With the right model, team and incentives, primary care physicians will continue to lead the charge for public health, regardless of the name we give them.

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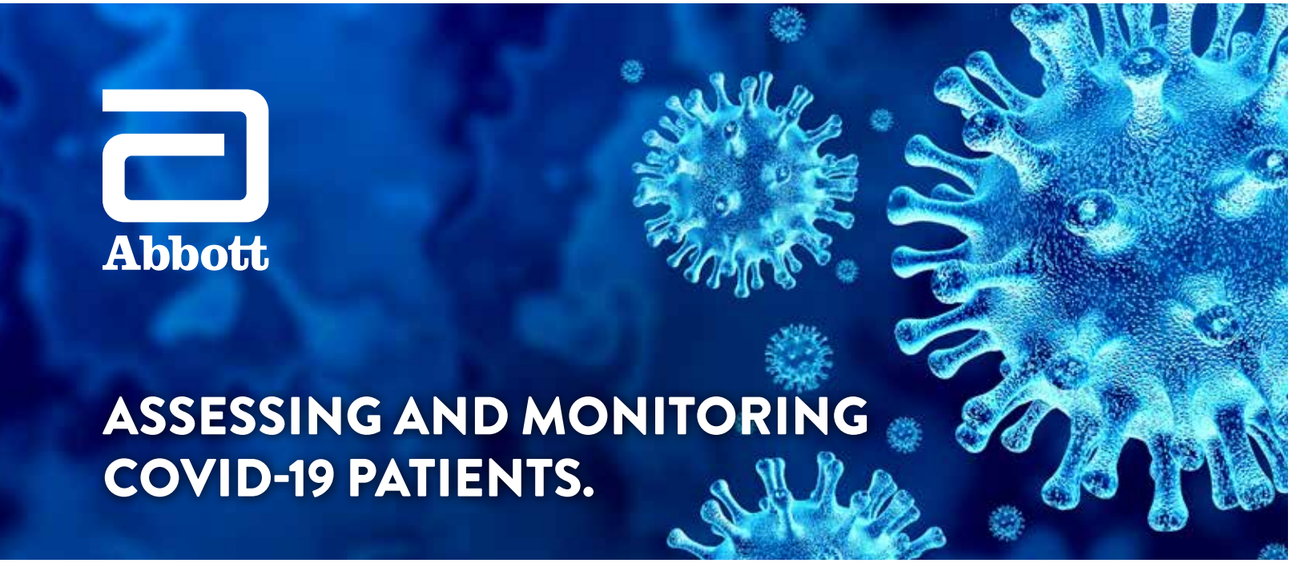
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  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
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The Abstract:

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University of Oxford Launches Phase 1 Trial for HIV Vaccine

Since the first report of AIDS in 1981, researchers have been looking for ways to combat HIV infections. Today, there are dozens of drugs available to help inhibit HIV, but as of yet, no vaccines have been approved to prevent HIV. HIV's ability to change and escape immune responses, has proved to be the biggest challenge in creating a safe and effective vaccine. That's why the announcement from University of Oxford that a Phase 1 Trial has been launched for an HIV vaccine was met with great excitement in early July. Tomas Hanke, the trial's lead researcher and Professor of Vaccine Immunology at the University of Oxford's Jenner Institute had this to say about the trial, "An effective HIV vaccine has been elusive for 40 years. This trial is the first in a series of evaluations of this novel vaccine strategy in both HIV-negative individuals for prevention and in people living with HIV for cure...Even in the broader context of increasing antiretroviral treatment and prevention, an HIV-1 vaccine remains the best solution and likely a key component to any strategy ending the AIDS epidemic."1

CRISPR Injection Treats Genetic Disease in Patients for the First Time

For years, scientists have been using the gene editor CRISPR for correcting mutations in laboratory settings. However, utilizing CRISPR technology to treat people with genetic diseases has faced a variety of obstacles, and specifically one large one: injecting CRISPR into a patient and making sure it slices the DNA in the correct spot. According to a recent article published in Science, researchers have successfully breached that large obstacle. In this trial, four men and two women suffering with the genetic disease transthyretin amyloidosis were injected a lipid particle containing two different RNAs: "an mRNA encoding the protein Cas, the CRISPR component that snips DNA, and a guide RNA to direct it to the gene for TTR. After Cas makes its cut, the cell's DNA repair machinery heals the break, but imperfectly, knocking out the activity of the gene."5 Results after about a month showed that three men had an 80-96% drop in transthyretin (a protein which builds up on the nerves of the heart causing pain and heart disease) levels. This research study is still in its early stages and there are still many unknowns such as side effects and if symptoms will continue to improve. But the early results are extremely promising and could open the door for CRISPR therapies. 5

Research Shows COVID mRNA Vaccine Does Not Affect Male Fertility

With rumors running rampant on social media and other outlets regarding the safety of the COVID mRNA vaccines, a new study published in JAMA sought to put to bed at least one of those rumors: that the COVID-19 mRNA vaccines cause a decrease in sperm parameters. The study hosted at the University of Miami recruited health volunteers aged 18-50 and were prescreened to make sure there were no underlying fertility issues. Two samples were taken after a prescribed number of days after the first and second doses. Results were then analyzed by trained professionals based on guidelines from the WHO. After analysis, this study showed that there was no significant decreases in any sperm parameter. 6

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New Treatment Candidate for Halting and Reversing the Effects of Dementia and Alzheimer's Disease

A recent study published in the International Journal of Molecular Sciences, a research team based at Tohoku University in Sendai Japan, have identified a new treatment candidate to halt and reverse the effects of neurodegenerative diseases such as dementia and Alzheimer's in mouse models.

Previous studies suggest that when a calcium channel is disrupted in a neurotransmitter, dopamine and acetylcholine releases are reduced, resulting in cognitive confusion and decreased motor function. This also leads to the buildup of aggregated proteins which inhibit proteasome activity leading to neuronal death. To combat this, researchers developed a disease modifying therapeutic, knows as SAK3 a T-type calcium channel enhancer. This therapeutic rescued neurons in most protein-misfolding, neurodegenerative diseases. The calcium channel enhancement is thought to trigger a change from resting to active in neuronal activity. According to the paper author, Kohi Fikunaga, professor emeritus in Tohoku University's Graduate School of Pharmaceutical Sciences, "Even after the onset of cognitive impairment, SAK3 administration significantly precented the progression of neurodegenerative behaviors in both motor dysfunction and cognition." Fikunaga went on to say, "SAK3 is the first compound targeting this regulatory activity in neurodegenerative disorders. SAK3 administration promotes the destruction of misfolded proteins, meaning the therapeutic has the potential to solve the problems of diverse protein misfolding diseases such as Parkinson's disease, Lewy body dementia and Huntington disease, in addition to Alzheimer's disease."2

Sequencing of over 600,000 Exomes Identifies 16 Variant Genes that Provide Protection from Obesity

In an article in the journal Science, researchers Parsa Akari et al. sought understanding in "how genes predispose individuals to, or protect individuals from, obesity."4 640,000 exomes were sequenced from the UK, US, and Mexico and identified 16 rare coding variants. One variant allele, GPR75, found in Mexican populations was associated with lower BMI. GPR75 was only found in 4 out of 10,000 sequenced people and were associated with "1.8 kg/m2 lower BMI, 5.3 kg lower bodyweight, and 54% lower odds of obesity in heterozygous carriers." In laboratory studies in mice with a knockout of GPR75 resulted in resistance to weight gain despite introduction of a high fat diet. Knockout mice also showed improved glycemic control and insulin sensitivity. Results were significant and lead researchers to believe that inhibition of GPR75 could be a therapeutic strategy for obesity.4

Increasing Evidence Suggests Controversial Sputnik COVID Vaccine is Safe and Effective

According to an article in the scientific journal, Nature, Russia's COVID-19 vaccine, Sputnik, is showing evidence from Russia and many other countries that suggests it is safe and effective. Sputnik, has been controversial from its early release in August 2020 before it ever completed Phase III trials. Even today after Phase III trials have been published, which showed the adenovirus vaccine was 91.6% effective at preventing symptomatic COVID-19 infection and 100% effective at preventing sever infection, "some scientists have criticized the authors for failing to provide full access to the raw data."3 Almost one year later from its release, the Russian vaccine has been approved for use in 67 countries, however it has yet to gain EUA from the WHO.

Utilizing two different adenoviruses for the first and second doses as a delivery mechanism for inserting the genetic code for the SARS-CoV-2 spike protein into human cells, has been shown to increase efficacy. The United Arab Emirates Ministry of Health reported a 97.8% efficacy in preventing symptomatic COVID-19 and just as trail results showed, a 100% efficacy in preventing sever disease in the 81,000 people who had received both doses. Another and as of yet, unpublished study from the Buenos Aires health ministry in Argentina, involving 40,387 vaccinated and 146,194 unvaccinated people ages 60-79 showed that a single does of Sputnik Light (a one shot variation of the vaccine) reduced symptomatic infections by 78.6% and deaths by 84.7%.3

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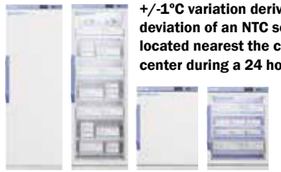
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Refrigerators & Freezers From 23 to 49 Cu.ft.

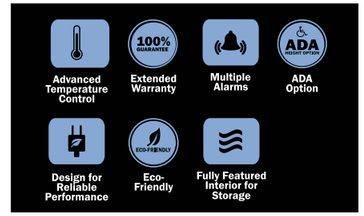


Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

9550

Advanced Temperature Control & Durable Performance

- Intelligent microprocessor digital temperature controller
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Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	865.00
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	878.00
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	965.00
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	969.00
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	1,060.00
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	1,072.00
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	1,284.00
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	1,349.00
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	1,788.00
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	1,801.00
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	1,970.00
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	1,983.00

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	2,466.00
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	2,811.00
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	3,634.00
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	4,186.00

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	2,804.00
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	4,299.00

Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator: Add the number of doses on hand (current inventory) from your last order form.

Public Vaccine _____
Private Vaccine + _____
Total doses = _____
Multiply (max inventory) x 1.25
Maximum doses = _____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO is indicated for the first-line treatment of patients with non–small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [tumor proportion score (TPS) ≥50%] as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is[1]:

- **Locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or[1]**
- **Metastatic[1]**



NOW APPROVED

As a first-line treatment option in **advanced**
NSCLC

Overall survival with LIBTAYO vs platinum-based chemotherapy in EMPOWER-Lung 1[1-3]*

ITT patient population (N=710)[1]

32% reduction in risk of death HR=0.68, *P*=0.0022[1]
Median OS: 22.1 months (95% CI, 17.7-NE) vs 14.3 months (95% CI, 11.7-19.2) (chemotherapy†), HR=0.68, *P*=0.0022[1]
Number of deaths: 30% of patients (108 out of 356 patients) with LIBTAYO and 40% of patients (141 out of 354 patients) with chemotherapy[1]

The EMPOWER-Lung 1 study was designed to enroll patients with PD-L1 ≥50%.[2]
- A total of 710 patients were enrolled and randomized. For some patients, it was later determined that PD-L1 biomarker testing was not conducted according to the instructions for use, and required retesting[2]
- An analysis was conducted in a subset of patients with known PD-L1 ≥50% (n=563). The analysis excluded 91 patients from the overall population whose PD-L1 status was unknown because their tumors could not be retested, and 56 patients from the overall population who had <50% PD-L1 expression[2] (LIBTAYO is not indicated in patients with <50% PD-L1 expression)

Known PD-L1 ≥50% patient population (n=563)[2,3]

43% reduction in risk of death HR=0.57, *P*=0.0002[2,3]
Median OS: NR (95% CI, 17.9-NE) vs 14.2 months (95% CI, 11.2-17.5) (chemotherapy†), HR=0.57, *P*=0.0002[2,3]
Number of deaths: 25% of patients (70 out of 283 patients) with LIBTAYO and 38% of patients (105 out of 280 patients) with chemotherapy[2,3]

PD-L1 expression was determined using the PD-L1 IHC 22C3 pharmDx assay.[1-3]

***Investigator's choice: Paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology.[1-3]**
† Platinum-based.[1-3]

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor; HR=hazard ratio; IHC=immunohistochemistry; ITT=intention-to-treat; NE=not evaluable; NR=not reached; NSCLC=non–small cell lung cancer; OS=overall survival; PD-L1=programmed death ligand 1; ROS1=ROS proto-oncogene 1, receptor tyrosine kinase.

Clinical safety data[1]

- LIBTAYO was permanently discontinued due to adverse reactions in 6% of patients;
- Adverse reactions resulting in permanent discontinuation in at least 2 patients were pneumonitis, pneumonia, ischemic stroke, and increased aspartate aminotransferase
- Serious adverse reactions occurred in 28% of patients receiving LIBTAYO;
- The most frequent serious adverse reactions in at least 2% of patients were pneumonia and pneumonitis

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1/PD-L1–blocking antibodies. The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

No dose reduction for LIBTAYO is recommended. In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO safety profile in EMPOWER-Lung 1[1]

Adverse reactions in ≥10% of patients[1]

Adverse reactions	LIBTAYO (n=355)		Chemotherapy (n=342)	
	All Grades, %	Grade 3-4, %	All Grades, %	Grade 3-4, %
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain*	26	0.6	27	1.5
Skin and subcutaneous tissue disorders				
Rash†	15	1.4	6	0
Blood and lymphatic system disorders				
Anemia	15	3.4	50	16
General disorders and administration site conditions				
Fatigue‡	14	1.1	26	2
Metabolism and nutrition disorders				
Decreased appetite	12	0.6	18	0.3
Infections and infestations				
Pneumonia§	11	5	12	5
Respiratory, thoracic, and mediastinal disorders				
Cough‖	11	0	8	0.3

*Musculoskeletal pain is a composite term that includes back pain, arthralgia, pain in extremity, musculoskeletal pain, musculoskeletal chest pain, bone pain, myalgia, neck pain, spinal pain, and musculoskeletal stiffness.
†Rash is a composite term that includes rash, dermatitis, urticaria, rash maculopapular, erythema, rash erythematous, rash pruritic, psoriasis, autoimmune dermatitis, dermatitis acneiform, dermatitis allergic, dermatitis atopic, dermatitis bullous, drug eruption, dyshidrotic eczema, lichen planus, and skin reaction.
‡Fatigue is a composite term that includes fatigue, asthenia, and malaise.
§Pneumonia is a composite term that includes atypical pneumonia, embolic pneumonia, lower respiratory tract infection, lung abscess, paracancerous pneumonia, pneumonia, pneumonia bacterial, and pneumonia klebsiella.
‖Cough is a composite term that includes cough and productive cough.
Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.03.

In patients who had no EGFR, ALK, or ROS1 aberrations:

EMPOWER-Lung 1 was designed to enroll advanced NSCLC patients with PD-L1 ≥50%[1]

Phase 3, large, randomized, multicenter, open-label, active-controlled trial (ITT population, N=710)[1,2]

Key eligibility criteria
- Treatment-naive metastatic NSCLC
- Locally advanced NSCLC, not candidates for surgical resection or definitive chemoradiation
- PD-L1 ≥50%
- ECOG PS 0 or 1

Permitted for enrollment
- Treated, clinically stable brain metastases¶
- Controlled hepatitis B, hepatitis C, or HIV
- Type 1 diabetes mellitus or hypothyroidism only requiring hormone replacement

R 1:1

- **LIBTAYO monotherapy 350 mg IV Q3W Treat until PD, unacceptable toxicity, or 108 weeks (n=356)** → PD → **Optional continuation of LIBTAYO + 4 cycles of chemotherapy****
- **Platinum-based chemotherapy 4 to 6 cycles# (n=354)** → PD → **Optional crossover to LIBTAYO monotherapy††**

Exclusion criteria included:
EGFR, ALK, or ROS1 genomic tumor aberrations, a medical condition that required systemic immunosuppression, uncontrolled infections with hepatitis B, hepatitis C, or HIV, autoimmune disease that required systemic therapy within 2 years of treatment, and never-smokers.

Primary endpoints[1]:
- OS and PFS

Secondary endpoints included[1,2]:
- ORR (key), DOR, and safety and tolerability

LIBTAYO was examined in a clinical study that included historically underrepresented patients with advanced NSCLC[1,2]:

In the LIBTAYO arm (ITT patient population) at baseline, 12% of patients had pretreated and stable brain metastases,¶ 18% had locally advanced disease, and 2% had controlled hepatitis B or hepatitis C. Patients with HIV were permitted to enroll, but none were recruited.[1,2,4]

¶Patients were eligible if they had been adequately treated and had neurologically returned to baseline for at least 2 weeks prior to randomization.[1]
#Investigator's choice: Paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology.[1]
**Patients who experienced IRC-assessed RECIST 1.1-defined progressive disease on therapy with LIBTAYO were permitted to continue treatment with LIBTAYO 350 mg Q3W for up to 108 additional weeks, along with the addition of histology-specific chemotherapy for 4 cycles until further disease progression was observed.[1]
††Patients who experienced IRC-assessed RECIST 1.1-defined progressive disease on chemotherapy were permitted to receive treatment with LIBTAYO for up to 108 weeks.[1,2]
Randomization was stratified by histology (nonsquamous vs squamous) and geographic region (Europe vs Asia vs rest of world).[1]
Median duration of exposure was 27.3 weeks (range, 9 days-115 weeks) for LIBTAYO vs 17.7 weeks (range, 18 days-86.7 weeks) for chemotherapy.[1]

DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; IRC=independent review committee; IV=intravenous; ORR=objective response rate; PD=progressive disease; PFS=progression-free survival; PS=performance status; Q3W=every 3 weeks; R=randomization; RECIST=Response Evaluation Criteria in Solid Tumors.

For more information, visit LIBTAYOhcp.com

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids.

Withhold or permanently discontinue LIBTAYO depending on severity. In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated pneumonitis: LIBTAYO can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 4 (0.5%), Grade 3 (0.5%), and Grade 2 (2.1%). Pneumonitis led to permanent discontinuation in 1.4% of patients and withholding of LIBTAYO in 2.1% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 58% of the 26 patients. Of the 17 patients in whom LIBTAYO was withheld, 9 reinitiated after symptom improvement; of these, 3/9 (33%) had recurrence of pneumonitis. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immune-mediated colitis: LIBTAYO can cause immune-mediated colitis. The primary component of immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory immune-mediated colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2.2% (18/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (1.1%). Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBTAYO in 1.5% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients. Of the 12 patients in whom LIBTAYO was withheld, 4 reinitiated LIBTAYO after symptom improvement; of these, 3/4 (75%) had recurrence. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immune-mediated hepatitis: LIBTAYO can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2% (16/810) of patients receiving LIBTAYO, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (1.4%), and Grade 2 (0.2%). Hepatitis led to permanent discontinuation of LIBTAYO in 1.2% of patients and withholding of LIBTAYO in 0.5% of patients. Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 19% (3/16) of these patients. Hepatitis resolved in 50% of the 16 patients. Of the 5 patients in whom LIBTAYO was withheld, 3 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence.

For hepatitis with no tumor involvement of the liver: Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 8 times the upper limit of normal (ULN) or if total bilirubin increases to more than 1.5 and up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 8 times the ULN or total bilirubin increases to more than 3 times the ULN.

For hepatitis with tumor involvement of the liver: Withhold LIBTAYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBTAYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times ULN or if total bilirubin increases to more than 3 times ULN. If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue LIBTAYO based on recommendations for hepatitis with no liver involvement.

Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immune-mediated endocrinopathies: For Grade 3 or 4 endocrinopathies, withhold until clinically stable or permanently discontinue depending on severity.

- **Adrenal insufficiency:** LIBTAYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBTAYO depending on severity. Adrenal insufficiency occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.4%). Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. LIBTAYO was not withheld in any patient due to adrenal insufficiency. Systemic corticosteroids were required in all patients with adrenal insufficiency; of these, 67% (2/3) remained on systemic corticosteroids. Adrenal insufficiency had not resolved in any patient at the time of data cutoff
- **Hypophysitis:** LIBTAYO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue depending on severity. Hypophysitis occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient and withholding of LIBTAYO in 1 (0.1%) patient. Systemic corticosteroids were required in 67% (2/3) of patients with hypophysitis. Hypophysitis had not resolved in any patient at the time of data cutoff
- **Thyroid disorders:** LIBTAYO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LIBTAYO depending on severity
- **Thyroiditis:** Thyroiditis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including Grade 2 (0.2%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis had not resolved in any patient at the time of data cutoff. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported
- **Hyperthyroidism:** Hyperthyroidism occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 0.5% of patients due to hyperthyroidism. Systemic corticosteroids were required in 3.8% (1/26) of patients. Hyperthyroidism resolved in 50% of 26 patients. Of the 4 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism
- **Hypothyroidism:** Hypothyroidism occurred in 7% (60/810) of patients receiving LIBTAYO, including Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. Hypothyroidism led to withholding of LIBTAYO in 1.1% of patients. Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 8.3% of the 60 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement; 1 required ongoing hormone replacement therapy
- **Type 1 diabetes mellitus, which can present with diabetic ketoacidosis:** Monitor for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBTAYO depending on severity. Type 1 diabetes mellitus occurred in 0.1% (1/810) of patients, including Grade 4 (0.1%). No patient discontinued treatment due to type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated nephritis with renal dysfunction: LIBTAYO can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including fatal (0.1%), Grade 3 (0.1%), and Grade 2 (0.4%). Nephritis led to permanent discontinuation in 0.1% of patients and withholding of LIBTAYO in 0.4% of patients. Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in 80% of the 5 patients. Of the 3 patients in whom LIBTAYO was withheld, 2 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence. Withhold LIBTAYO for Grade 2 or 3 increased blood creatinine, and permanently discontinue for Grade 4 increased blood creatinine. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immune-mediated dermatologic adverse reactions: LIBTAYO can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) has occurred with PD-1/PD-L1–blocking antibodies. Immune-mediated dermatologic adverse reactions occurred in 1.6% (13/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (0.6%). Immune-mediated dermatologic adverse reactions led to permanent discontinuation in 0.1% of patients and withholding of LIBTAYO in 1.4% of patients. Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 69% of the 13 patients. Of the 11 patients in whom LIBTAYO was withheld for dermatologic adverse reactions, 7 reinitiated LIBTAYO after symptom improvement; of these, 43% (3/7) had recurrence of the dermatologic adverse reaction. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold LIBTAYO for suspected SJS, TEN, or DRESS. Permanently discontinue LIBTAYO for confirmed SJS, TEN, or DRESS. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 810 patients who received LIBTAYO or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

- **Cardiac/vascular:** Myocarditis, pericarditis, and vasculitis. Permanently discontinue for Grades 2, 3, or 4 myocarditis
- **Nervous system:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy. Withhold for Grade 2 neurological toxicities and permanently discontinue for Grades 3 or 4 neurological toxicities. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis
- **Musculoskeletal and connective tissue:** Myositis/polymyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
- **Endocrine:** Hypoparathyroidism
- **Other (hematologic/immune):** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.1% of patients receiving LIBTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. The most common symptoms of infusion-related reaction were nausea, pyrexia, rash, and dyspnea. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Complications of allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse Reactions

- In the pooled safety analysis of 810 patients, the most common adverse reactions (≥15%) with LIBTAYO were musculoskeletal pain, fatigue, rash, and diarrhea
- In the pooled safety analysis of 810 patients, the most common Grade 3-4 laboratory abnormalities (≥2%) with LIBTAYO were lymphopenia, hyponatremia, hypophosphatemia, increased aspartate aminotransferase, anemia, and hyperkalemia

Use in Specific Populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

Please see Brief Summary of full Prescribing Information on the following pages.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. *Lancet*. 2021;397(10274):592-604. Supplementary material available at: https://www.sciencedirect.com/science/article/abs/pii/S0140673621002282. Accessed February 13, 2021. **3.** PD-L1 IHC 22C3 pharmDx [instructions for use]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2021. **4.** Data on file. Regeneron Pharmaceuticals, Inc.

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LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) injection, for intravenous use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.3 Non-Small Cell Lung Cancer

LIBTAYO is indicated for the first-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test *[see Dosage and Administration (2.1) in the full prescribing information]*), with no EGFR, ALK or ROS1 aberrations, and is:

- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
- metastatic.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

LIBTAYO is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*. In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Immune-Mediated Pneumonitis

LIBTAYO can cause immune-mediated pneumonitis. The definition of immune-mediated pneumonitis included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. In patients treated with other PD-1/PD-L1 blocking antibodies the incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 4 (0.5%), Grade 3 (0.5%), and Grade 2 (2.1%) adverse reactions. Pneumonitis led to permanent discontinuation of LIBTAYO in 1.4% of patients and withholding of LIBTAYO in 2.1% of the patients.

Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 58% of the 26 patients. Of the 17 patients in whom LIBTAYO was withheld for pneumonitis, 9 reinitiated LIBTAYO after symptom improvement; of these, 3/9 (33%) had recurrence of pneumonitis.

Immune-Mediated Colitis

LIBTAYO can cause immune-mediated colitis. The definition of immune-mediated colitis included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. The primary component of the immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1 blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 2.2% (18/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (1.1%) adverse reactions. Colitis led to permanent discontinuation of LIBTAYO in 0.4% of patients and withholding of LIBTAYO in 1.5% of patients.

Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients. Of the 12 patients in whom LIBTAYO was withheld for colitis, 4 reinitiated LIBTAYO after symptom improvement; of these, 3/4 (75%) had recurrence of colitis.

Immune-Mediated Hepatitis

LIBTAYO can cause immune-mediated hepatitis. The definition of immune-mediated hepatitis included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology.

Immune-mediated hepatitis occurred in 2% (16/810) of patients receiving LIBTAYO, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (1.4%), and Grade 2 (0.2%) adverse reactions. Hepatitis led to permanent discontinuation of LIBTAYO in 1.2% of patients and withholding of LIBTAYO in 0.5% of patients.

Systemic corticosteroids were required in all patients with hepatitis. Nineteen percent (19%) of these patients (3/16) required additional immunosuppression with mycophenolate. Hepatitis resolved in 50% of the 16 patients. Of the 5 patients in whom LIBTAYO was withheld for hepatitis, 3 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

LIBTAYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*.

Adrenal insufficiency occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.4%) adverse reactions. Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. LIBTAYO was not withheld in any patient due to adrenal insufficiency. Systemic corticosteroids were required in all patients with adrenal insufficiency; of these 67% (2/3) remained on systemic corticosteroids. Adrenal insufficiency had not resolved in any patient at the time of data cutoff.

Hypophysitis

LIBTAYO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*.

Hypophysitis occurred in 0.4% (3/810) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient and withholding of LIBTAYO in 1 (0.1%) patient. Systemic corticosteroids were required in 67% (2/3) patients with hypophysitis. Hypophysitis had not resolved in any patient at the time of data cutoff.

Thyroid Disorders

LIBTAYO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*.

Thyroiditis: Thyroiditis occurred in 0.6% (5/810) of patients receiving LIBTAYO, including Grade 2 (0.2%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis had not resolved in any patient at the time of data cutoff.

Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported.

Hyperthyroidism: Hyperthyroidism occurred in 3.2% (26/810) of patients receiving LIBTAYO, including Grade 2 (0.9%) adverse reactions. No patient discontinued treatment due to hyperthyroidism. Hyperthyroidism led to withholding of LIBTAYO in 0.5% of patients.

Systemic corticosteroids were required in 3.8% (1/26) of patients with hyperthyroidism. Hyperthyroidism resolved in 50% of the 26 patients. Of the 4 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism.

Hypothyroidism: Hypothyroidism occurred in 7% (60/810) of patients receiving LIBTAYO, including Grade 2 (6%) adverse reactions. Hypothyroidism led to permanent discontinuation of LIBTAYO in 1 (0.1%) patient. Hypothyroidism led to withholding of LIBTAYO in 1.1% of patients.

Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 8.3% of the 60 patients. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.

Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement; 1 required ongoing hormone replacement therapy.

Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis.

Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*.

Type 1 diabetes mellitus occurred in 0.1% (1/810) of patients, including Grade 4 (0.1%) adverse reactions. No patient discontinued treatment due to Type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients.

Immune-Mediated Nephritis with Renal Dysfunction

LIBTAYO can cause immune-mediated nephritis. The definition of immune-mediated nephritis included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology.

Immune-mediated nephritis occurred in 0.6% (5/810) patients receiving LIBTAYO, including fatal (0.1%), Grade 3 (0.1%) and Grade 2 (0.4%) adverse reactions. Nephritis led to permanent discontinuation of LIBTAYO in 0.1% of patients and withholding of LIBTAYO in 0.4% of patients.

Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in 80% of the 5 patients. Of the 3 patients in whom LIBTAYO was withheld for nephritis, 2 reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of nephritis.

Immune-Mediated Dermatologic Adverse Reactions

LIBTAYO can cause immune-mediated rash or dermatitis. The definition of immune-mediated dermatologic adverse reaction included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and DRESS (Drug Rash with Eosinophilia and Systemic Symptoms), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue LIBTAYO depending on severity *[see Dosage and Administration (2.3) in the full prescribing information]*.

Immune-mediated dermatologic adverse reactions occurred in 1.6% (13/810) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (0.6%) adverse reactions. Dermatologic adverse reactions led to permanent discontinuation of LIBTAYO in 0.1% of patients and withholding of LIBTAYO in 1.4% of patients.

Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 69% of the 13 patients. Of the 11 patients in whom LIBTAYO was withheld for dermatologic adverse reaction, 7 reinitiated LIBTAYO after symptom improvement; of these 43% (3/7) had recurrence of the dermatologic adverse reaction.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of < 1% in 810 patients who received LIBTAYO or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Cardiac/Vascular: Myocarditis, pericarditis, vasculitis

Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome / myasthenia gravis (including exacerbation), Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis

Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Endocrine: Hypoparathyroidism

Other (Hematologic/Immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

5.2 Infusion-Related Reactions

Severe infusion-related reactions (Grade 3) occurred in 0.1% of patients receiving LIBTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. The most common symptoms of infusion-related reaction were nausea, pyrexia, rash and dyspnea.

Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction *[see Dosage and Administration (2.3) in the full prescribing information]*.

5.3 Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

5.4 Embryo-Fetal Toxicity

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling.

- Severe and Fatal Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.2)]*
- Complications of Allogeneic HSCT *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described in Warnings and Precautions reflect exposure to LIBTAYO as a single agent in 810 patients in three open-label, single-arm, multicohort studies (Study 1423, Study 1540 and Study 1620), and one open-label randomized multi-center study (Study 1624). These studies included 219 patients with advanced CSCC (Studies 1540 and 1423), 132 patients with advanced BCC (Study 1620), 355 patients with NSCLC (Study 1624), and 104 patients with other advanced solid tumors (Study 1423). LIBTAYO was administered intravenously at doses of 3 mg/kg every 2 weeks (n=235), 350 mg every 3 weeks (n=543), or other doses (n=32; 1 mg/kg every 2 weeks, 10 mg/kg every 2 weeks, 200 mg every 2 weeks). Among the 810 patients, 57% were exposed for ≥ 6 months and 25% were exposed for ≥ 12 months. In this pooled safety population, the most common adverse reactions (≥15%) were musculoskeletal pain, fatigue, rash, and diarrhea. The most common Grade 3-4 laboratory abnormalities (≥2%) were lymphopenia, hyponatremia, hypophosphatemia, increased aspartate aminotransferase, anemia, and hyperkalemia.

Non-Small Cell Lung Cancer (NSCLC)

The safety of LIBTAYO was evaluated in 355 patients with locally advanced or metastatic NSCLC in Study 1624 *[see Clinical Studies (14.3) in the full prescribing information]*. Patients received LIBTAYO 350 mg every 3 weeks (n=355) or investigator's choice of chemotherapy (n=342), consisting of paclitaxel plus cisplatin or carboplatin; gemcitabine plus cisplatin or carboplatin; or pemetrexed plus cisplatin or carboplatin followed by optional pemetrexed maintenance. The median duration of exposure was 27.3 weeks (9 days to 115 weeks) in the LIBTAYO group and 17.7 weeks (18 days to 86.7 weeks) in the chemotherapy group. In the LIBTAYO group, 54% of patients were exposed to LIBTAYO for ≥ 6 months and 22 % were exposed for ≥ 12 months.

The safety population characteristics were: median age of 63 years (31 to 79 years), 44% of patients 65 or older, 88% male, 86% White, 82% had metastatic disease and 18% had locally advanced disease and ECOG performance score (PS) of 0 (27%) and 1 (73%).

LIBTAYO was permanently discontinued due to adverse reactions in 6% of patients; adverse reactions resulting in permanent discontinuation in at least 2 patients were pneumonitis, pneumonia, ischemic stroke and increased aspartate aminotransferase. Serious adverse reactions occurred in 28% of patients. The most frequent serious adverse reactions in at least 2% of patients were pneumonia and pneumonitis.

Table 6 summarizes the adverse reactions that occurred in ≥ 10% of patients and Table 7 summarizes Grade 3 or 4 laboratory abnormalities in patients receiving LIBTAYO.

Table 6: Adverse Reactions in ≥ 10% of Patients with Locally Advanced or Metastatic NSCLC Receiving LIBTAYO in Study 1624

Adverse Reactions	LIBTAYO N=355		Chemotherapy N=342	
	All Grades %	Grades 3-4 %	All Grades %	Grades 3-4 %
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[a]	26	0.6	27	1.5
Skin and subcutaneous tissue disorders				
Rash[b]	15	1.4	6	0
Blood and lymphatic system disorders				
Anemia	15	3.4	50	16
General disorders and administration site conditions				
Fatigue[c]	14	1.1	26	2
Metabolism and nutrition disorders				
Decreased appetite	12	0.6	18	0.3
Infections and infestations				
Pneumonia[d]	11	5	12	5
Respiratory, thoracic and mediastinal disorders				
Cough[e]	11	0	8	0.3

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03

a. Musculoskeletal pain is a composite term that includes back pain, arthralgia, pain in extremity, musculoskeletal pain, musculoskeletal chest pain, bone pain, myalgia, neck pain, spinal pain, and musculoskeletal stiffness
b. Rash is a composite term that includes rash, dermatitis, urticaria, rash maculo-papular, erythema, rash erythematous, rash pruritic, psoriasis, autoimmune dermatitis, dermatitis acneiform, dermatitis allergic, dermatitis atopic, dermatitis bullous, drug eruption, dyshidrotic eczema, lichen planus, and skin reaction
c. Fatigue is a composite term that includes fatigue, asthenia, and malaise
d. Pneumonia is a composite term that includes atypical pneumonia, embolic pneumonia, lower respiratory tract infection, lung abscess, paracancerous pneumonia, pneumonia, pneumonia bacterial, and pneumonia klebsiella
e. Cough is a composite term that includes cough and productive cough

Table 7: Grade 3 or 4 Laboratory Abnormalities Worsening from Baseline in ≥1% of Patients with Locally Advanced or Metastatic NSCLC Receiving LIBTAYO in Study 1624

Laboratory Abnormality	LIBTAYO N=355	Chemotherapy N=342
	Grades 3-4[a] %	
Chemistry		
Increased aspartate aminotransferase	3.9	1.2
Increased alanine aminotransferase	2.7	0.3
Increased alkaline phosphatase	2.4	0.3
Increased blood bilirubin	2.1	0.3
Hypoalbuminemia	1.8	1.3
Increased creatinine	1.2	1.6
Hematology		
Lymphopenia	7	9
Anemia	2.7	16
Electrolytes		
Hyponatremia	6	7
Hyperkalemia	4.2	1.9
Hypocalcemia	3.9	3.4
Hypophosphatemia	2.4	4.1
Hypermagnesemia	2.1	1.6
Hypokalemia	1.5	2.2
Hypercalcemia	1.2	2.2

Toxicity graded per NCI CTCAE v. 4.03

a. Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to cemiplimab-rwlc in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Anti-drug antibodies (ADA) were tested in 823 patients who received LIBTAYO. The incidence of cemiplimab-rwlc treatment-emergent ADAs was 2.2% using an electrochemiluminescent (ECL) bridging immunoassay; 0.4% were persistent ADA responses. In the patients who developed anti-cemiplimab-rwlc antibodies, there was no evidence of an altered pharmacokinetic profile of cemiplimab-rwlc.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in the full prescribing information]*. There are no available data on the use of LIBTAYO in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death *(see Data)*. Human IgG4 immunoglobulins (IgG4) are known to cross the placenta; therefore, LIBTAYO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Animal reproduction studies have not been conducted with LIBTAYO to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering LIBTAYO during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to cemiplimab-rwlc may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of cemiplimab-rwlc in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO *[see Use in Specific Populations (8.1)]*.

Contraception

LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Females

Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

8.4 Pediatric Use

The safety and effectiveness of LIBTAYO have not been established in pediatric patients.

8.5 Geriatric Use

Of the 810 patients who received LIBTAYO in clinical studies, 32% were 65 years up to 75 years and 22% were 75 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.

Of the 219 patients with mCSCC or laCSCC who received LIBTAYO in clinical studies, 34% were 65 years up to 75 years and 41% were 75 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.

Of the 132 patients with BCC who received LIBTAYO in Study 1620, 27% were 65 years up to 75 years, and 32% were 75 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.

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