2022 | Issue 6

Physicians office Resource

Resources for You, Your Patients, & Your Practice

Comprehensive In-office Diabetes Testing

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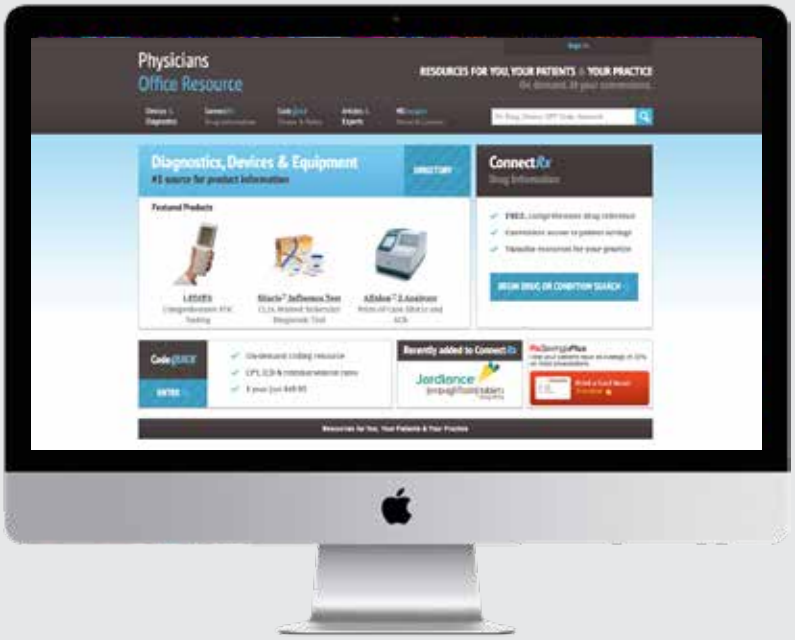
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1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

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MEETING THE GOALS OF VALUE-BASED CARE IN CHRONIC DISEASE MANAGEMENT

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Chronic diseases are the leading causes of death and disability in the U.S. and major drivers of the nation's rising healthcare costs.

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MDecapes: A DREAM DESTIN-ATION

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This luxury boutique hotel is just a year old and has quickly become the place in Northwest Florida to see and be seen. I'm enthralled as I enter the lobby with the expansive ceilings, fresh floral arrangements, extensive marble, curated artwork, modern crystal fixtures, and design concept.

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WHY NO ONE RESPONDS TO "WHY DID YOU WANT TO BECOME A DOCTOR?" WITH ANYTHING STARTING WITH "THE SALARY —"

—

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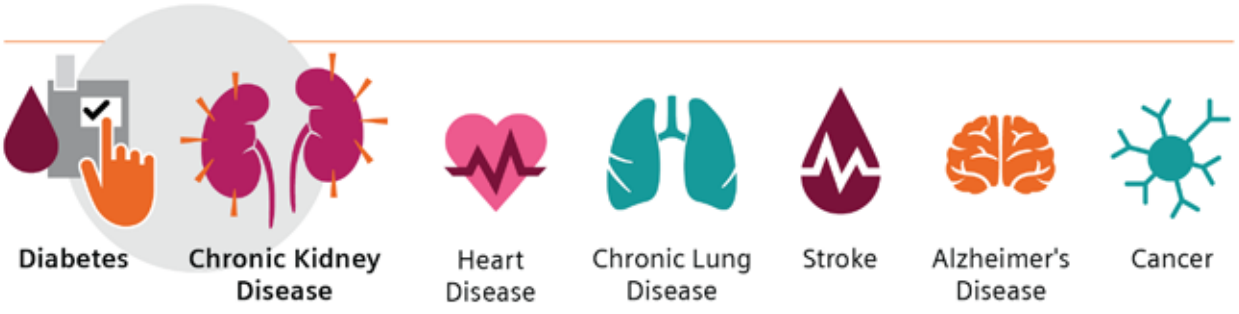
FEATURE

MEETING THE GOALS OF VALUE-BASED CARE IN CHRONIC DISEASE MANAGEMENT

BY SUSAN GARRAMONE, SENIOR CLINICAL MARKETING MANAGER
SIEMENS HEALTHINEERS

Chronic diseases are the leading causes of death and disability in the U.S. and major drivers of the nation's rising healthcare costs.[1] Per the Centers for Disease Control and Prevention, the top seven chronic diseases include heart disease, cancer, chronic lung disease, stroke, Alzheimer's disease, diabetes, and chronic kidney disease (CKD). In the United States, 60% of adults have one chronic disease, and 40% are reported as having two or more.[1] The costs of these chronic diseases account for nearly 86% of healthcare costs.[2]

With these staggering statistics, chronic disease management has become one of the most important priorities for healthcare organizations today and the driving force behind value-based care: the measured improvement in a patient's health outcomes for the cost of achieving that improvement.[3]



Value-based Care (VBC)

The goal of value-based care is to standardize healthcare processes and develop proactive best practices for patient care to prevent progression and avoid complications of disease before they start. The Value-Based Care (VBC) model centers around patient and provider accountability, shifting emphasis from fee-for-service.[5] In this model, physician and hospital payments are based on patient outcomes, rather than volume-based metrics such as the number of patients seen, or procedures performed. The focus on patient outcomes is intended to help reduce healthcare costs while improving overall patient health and well-being.[5]

Patients seeking care for most of the high-cost chronic conditions, including diabetes and CKD, rely heavily on primary care physicians.[6] In fact, primary care physicians

treat at least 90% of patients with diabetes in the United States.[7] Regular visits with primary care physicians can involve screenings, checkups, monitoring and coordinating treatment, and patient education to help manage chronic conditions.

Value-based care may provide earned financial relief to primary care practices while allowing clinicians to strengthen the rewarding patient relationships that are the backbone of primary care.[8] In a joint survey by the American Academy of Family Physicians and CompHealth, 87% of providers said the best part of their job was "interacting with patients and helping patients."[9] Unfortunately, to achieve success in fee-for-service models, providers spend less time with patients, often addressing immediate needs but not underlying causes.[9] Value-based care changes this dynamic, as it aligns incentives with the physician's focus on patient outcomes rather than volume. Additionally, moving from a patient-volume model improves the experience of both the patient and physician, and may allow more time for valuable consultation.[9,10] Overall, value-based care helps address the goals of the Quadruple Aim: better outcomes, lower costs, improved patient experience, and improved clinician experience.



Quality Measures and Quality Payment Programs

Quality measures are standards for evaluating performance when caring for patients. They are developed by both private and public-sector organizations and are generally based on the current clinical guidelines or literature reviews. Quality measures are used to not only benchmark individual clinicians and distribute bonus payments, but also to evaluate facilities, health systems, treatments, and care coordination.[11] There are several quality-payment programs and performance-measurement sets designed to hold providers accountable for quality, assist in identifying opportunities for improvement, and monitor progress over time.

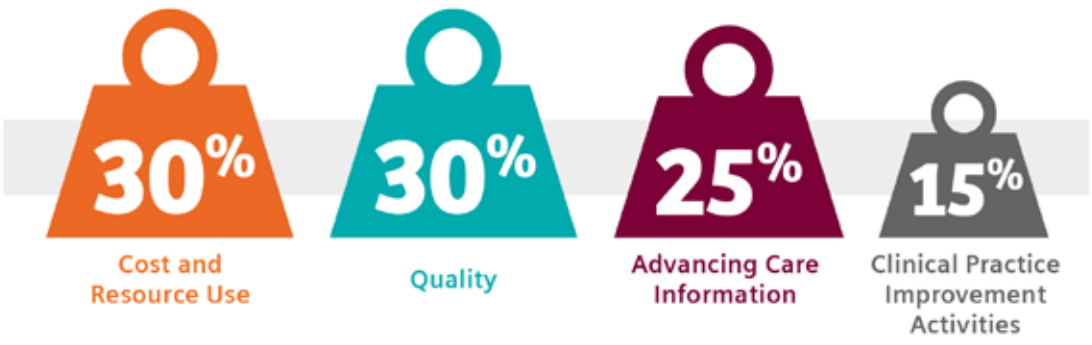
The Centers for Medicare & Medicaid Services (CMS) is the largest payer of healthcare services in the United States.[12] CMS is also the primary driver of changes in payment and delivery models and incorporation of value-based purchasing of healthcare services based on incentives.[12] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established a physician payment system that incentivizes improvements in U.S. healthcare. Under MACRA, physicians participate in the Quality Payment Program (QPP), depending on eligibility, payment impact, and other factors, through the Merit-Based Incentive Payment System (MIPS) or through Advanced Alternative Payment Models (APM), such as risk-bearing accountable care organizations (ACOs).[13]

All eligible clinicians must choose to participate in either the MIPS or the APMs track and meet eligibility based on specific requirements.[13] MIPS is the default program for all providers. In the MIPS program, providers' performance is measured in four categories: quality, costs, the use of certified EHR, and improvements in clinical practice. Each category is weighted, and providers receive a score between 0 and 100.[13,14] This score is then used to adjust payments. Under APMs, there are financial incentives related to the level of provider financial risk and the quality of care provided.[14]

Medical Access & CHIP Reauthorization Act (MACRA)[15]

	MIPS Merit-based Incentive	APMs Alternate Payment Methods
Who is Eligible?	Default QPP for physicians unless you have a low volume of Medicare patients or participants in Advanced APMs	An alternative option to MIPS for physicians with significant participation in more advanced levels of value-based activities
How is Payment Impacted?	There is a sliding scale of rewards and penalties starting at 9% in 2022	Advanced APM entities will receive a 5% Medicare Part B incentive payment from 2019–2024
How are Physicians Evaluated?	Four ways of evaluating: **1.** Quality reporting **2.** Advancing Care Information **3.** Cost (value-based modifier) **4.** Improvement activities	Advanced APMs have their own reporting requirements and are exempt from MIPS reporting. MIPS APMs fall under MIPS reporting system
2020 General Participation[16]		
	933,547 Clinicians Enrolled in MIPS	**237,315** Clinicians Enrolled in APMs

2022 MIPs Performance Categories and Weights (%)



In 2022, MIPS scoring is weighted as follows: Quality (30%), Advancing Care Information (25%), Clinical Practice Improvement Activities (15%), and Cost and Resource Use (30%). The maximum payment adjustment for 2022 is ±9%.[17]

The National Committee for Quality Assurance (NCQA) established a comprehensive set of standardized performance measures, the Healthcare Effectiveness Data and Information Set (HEDIS), to give purchasers and consumers a way to reliably compare health plan performance.[18] 90% of U.S. health plans, including commercial, Medicare, and Medicaid health plans, use HEDIS measurement targets in determining quality incentive payments.[18] Several HEDIS measures align with and are included in MIPS criteria.

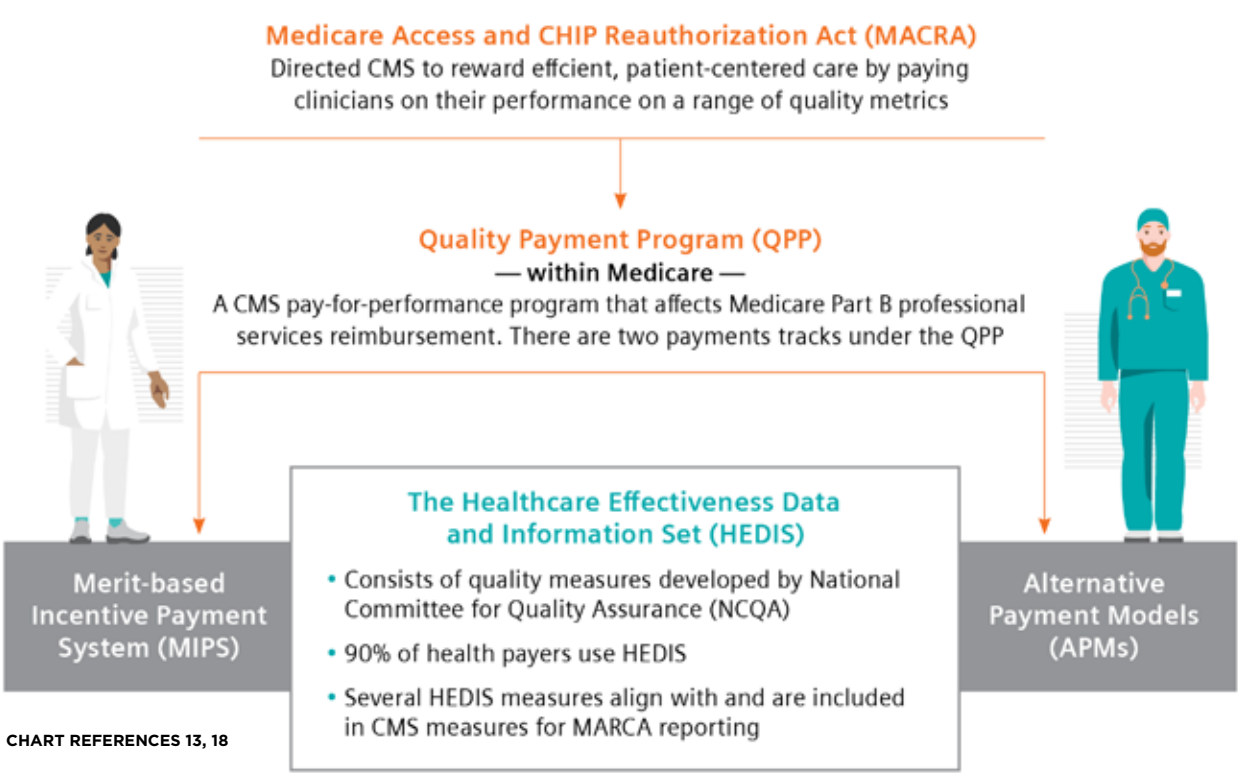


CHART REFERENCES 13, 18

Quality Measures in Diabetes and CKD

Diabetes is an ideal target for prevention strategies, as it is a major risk factor for other serious chronic conditions, including CKD. In the U.S., 37 million people are diagnosed with diabetes.[19] This epidemic is responsible for an estimated $327 billion in annual medical and lost productivity costs.[20]

Additionally, 1 in 3 adults with diabetes also have CKD, responsible for more than $81 billion in annual Medicare costs.[21,22] For those at risk for diabetes and CKD, early identification can prevent disease. For those with disease, early identification and treatment and routine monitoring can control disease progression and prevent related complications.[23] On this basis, both diabetes and CKD are good targets for value-based care, where there is a desire to positively manage long-term outcomes while containing total cost of care in these growing populations. As such, diabetes and kidney health quality measures are often a focus of quality payment programs.

Guidelines call for routine testing of hemoglobin A1c (HbA1c) and urine albumin-creatinine ratio (uACR) for disease monitoring and management.[24,25] However, the literature demonstrates that only approximately 70% and 32% of patients with diabetes follow the testing guidelines for HbA1c and uACR, respectively.[26,27]

Key quality measures in diabetes care are HbA1c control for patients with diabetes and uACR for patients with diabetes and kidney disease.[28,29]

The population health challenge presented by diabetes, and the need for action, have been recognized for a long time. In 1998, to assess quality of care in diabetes management, the Centers for Medicare & Medicaid Services (CMS), the National Committee on Quality Assurance (NCQA), and the American Diabetes Association (ADA) led the first national effort to develop a set of performance measures for diabetes.[30] These quality performance measures have since been widely adopted for assessment in Medicare, Medicaid, and commercial health plans, as a driver toward value-based care.[31]

Both MIPS and HEDIS quality measures for 2022 include measures for guideline supported HbA1c and uACR testing (Table 1).[28,29]

Table 1. HEDIS and MIPS 2022 quality measures for HbA1c and uACR testing.

Quality Program	Measure Name	Measure Description
HEDIS[28]	Hemoglobin A1c Control for Patients with Diabetes	The percentage of members 18–75 years of age with diabetes (types 1 and 2) whose hemoglobin A1c (HbA1c) was at the following levels during the measurement year: • HbA1c control (<8.0%) • HbA1c poor control (>9.0%)
HEDIS[28]	Kidney Health Evaluation for Patients with Diabetes	The percentage of members 18–85 years of age with diabetes (type 1 and type 2) who received a kidney health evaluation, defined by an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR), during the measurement year
MIPS[29]	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period
MIPS[29]	Diabetes: Medical Attention for Nephropathy	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period. Performance met: • Positive microalbuminuria test result documented and reviewed • Negative microalbuminuria test result documented and reviewed

A Path to Success in Quality Programs with Point-of-care Testing

Managing patients diagnosed with diabetes according to clinical guidelines is critically important, yet overall testing compliance is poor.[26,27] Point-of-care testing (POCT), clinical laboratory testing at the site of patient care, has been described as a quick, easy, reliable method for monitoring diabetes, and improving test adherence, in the primary care office setting.[32] POCT enables the physician to perform diagnostic testing during an office-visit and affords the opportunity for immediate patient-physician consultation and intervention, eliminating potential loss and cost of follow-up associated with traditional laboratory (send-out) testing.[32] In fact, the ADA has stated that "The use of point-of-care A1C testing may provide an opportunity for more timely treatment changes during encounters between patients and provider."[24]

There is a growing body of evidence supporting the benefits of point-of-care testing to meet goals:

- A study by Crocker et al. demonstrated that POC HbA1c testing led to 3.7 times decreased likelihood of missing HbA1c testing.[32]

- A second study by Crocker demonstrated that point-of-care HbA1c testing "can significantly improve clinical operations with cost reductions through improved practice efficiency," realizing a potential savings from improved efficiency of $24.64 per patient.[33] This savings was achieved through a reduction in the number of calls, letters and additional patient visits required following implementation of POCT.

- A recent study by Christofides stated, "Access to uACR testing may be improved by using Clinical Laboratory Improvements Amendments (CLIA)-waived point of care UACR testing options, that is, those approved for use closer to the patient and not necessarily in a central laboratory," and noted that using a CLIA-waived POC uACR option was a means to optimize test ordering.[34]

- A study by Schultes et al. found that the implementation of uACR POCT in daily general practice can improve the diagnosis and treatment of diabetic kidney disease (DKD).[35] The availability of uACR results at the time of the consultation led physicians to make medication adjustments to 18.5% of the patients enrolled in the study.[35]

The findings reported in these papers, and others they cite, suggest implementation of POCT may help busy practices achieve quality measures with increased testing adherence while decreasing operating costs through improved practice efficiency.[32-35]

Conclusion

The goal of value-based care is to cost-effectively improve patient outcomes. Value-based care models reward providers for efficient and effective patient care based on reported quality measures. Chronic conditions such as diabetes and CKD are ideal targets for value-based care because early detection and coordinated intervention can stop disease progression, improve quality of life, and reduce healthcare costs.

Quality measures in both diabetes and CKD are focused on guideline-recommended diagnostic testing. Adoption of point-of-care testing can improve test adherence while bringing increased value to patient office visits. Availability of real-time test results enables immediate consultation and faster intervention and treatment. This facilitation of care may lead to improved patient outcomes and decreased overall diabetes-related healthcare costs, meeting the goals of value-based care.

References

1. https://www.cdc.gov/chronicdisease/about/index.htm#:~:text=Many%20chronic%20diseases%20 are%20caused. Accessed 4-13-22.

2. Holman HR. The relation of the chronic disease epidemic to the health care crisis. ACR Open Rheumatol. 2020 Mar;2(3):167-73. doi: 10.1002/acr2.11114. Epub 2020 Feb 19. PMID: 32073759; PMCID: PMC7077778.

3. https://www.nachc.org/wp-content/uploads/2017/05/CHF-Winter-Spring-2017-Facing-the-Transition.pdf. Accessed 4-13-22.

4. Petersen R, et al. Improving population health by incorporating chronic disease and injury prevention into value-based care models. North Carolina Med J. 2016;77(4):257-60. doi: 10.18043/ncm.77.4.257.

5. https://my.clevelandclinic.org/health/articles/15938-value-based-care. Accessed 4-13-22.

6. Sharma MA, et al. Patients with high-cost chronic conditions rely heavily on primary care physicians. J Am Board Fam Med. 2014;27(1):11-2. doi: 10.3122/jabfm.2014.01.130128.

7. Davidson JA. The increasing role of primary care physicians in caring for patients with type 2 diabetes mellitus. Mayo Clin Proc. 2010;85(12 Suppl):S3-S4. doi: 10.4065/mcp.2010.0466

8. https://www.capphysicians.com/articles/overview-value-based-care-primary-care-practices. Accessed 4-13-22.

9. https://www.priviahealth.com/blog/how-the-quadruple-aim-and-value-based-care-intersect/. Accessed 4-13-22.

10. Teisberg E, Wallace S, O'Hara S. Defining and implementing value-based health care: a strategic framework. Acad Med. 2020;95(5):682-5. doi: 10.1097/ACM.0000000000003122.

11. https://carejourney.com/physician-quality-and-why-it-is-important/ABCs of Measurement. Accessed 4-13-22.

12. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Programs. Accessed 4-13-22.

13. https://www.aapc.com/macra/macra.aspx. Accessed 4-13-22.

14. https://checkpointehr.com/blog/difference-between-mips-and-apms/. Accessed 4-13-22.

15. https://www.myavls.org/member-resources/macra-resources.html . Accessed 4-13-22.

16. https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1783/QPP%202020%20Participation%20Results%20Infographic.pdf . Accessed 4-13-22.

17. https://mdinteractive.com/mips-blog/cms-releases-2022-mips-final-rule-key-takeaways. Accessed 4-13-22.

18. https://healthpayerintelligence.com/news/how-hedis-cms-star-ratings-cqms-impact-healthcare-payers. Accessed 4-13-22.

19. https://www.cdc.gov/diabetes/basics/quick-facts.html . Accessed 4-13-22.

20. American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. Diabetes Care. 2018;41(5):917-28. doi: 10.2337/dci18-0007.

21. https://www.cdc.gov/kidneydisease/prevention-risk/make-the-connection.html. Accessed 4-13-22.

22. https://adr.usrds.org/2020/chronic-kidney-disease/6-health-care-expenditures-for-persons-with-ckd. Accessed 4-13-22.

23. https://www.consultant360.com/articles/diabetes-and-chronic-kidney-disease-prevention-early-recognition-and-treatment. Accessed 4-13-22.

24. American Diabetes Association. Glycemic targets: standards of medical care in diabetes—2021. Diabetes Care. 2021 Jan;44(-Suppl 1): S73-S84. Available from: https://doi.org/10.2337/dc21-S006. Accessed 4-13-22.

25. American Diabetes Association Professional Practice Committee, et al. 11. Chronic kidney disease and risk management: standards of medical care in diabetes-2022. Diabetes Care. 2022;45(Suppl_1): S175-S184. doi: 10.2337/dc22-S011.

26. https://www.cdc.gov/diabetes/pdfs/library/Diabetes-Report-Card-2019-508.pdf. Accessed 12-17-21. Accessed 4-13-22.

27. Alfego D, et al. Chronic kidney disease testing among at-risk adults in the U.S. remains low: real-world evidence from a national laboratory database. Diabetes Care. 2021;44(9):2025-32. doi:10.2337/dc21-0723.

28. https://www.ncqa.org/wp-content/uploads/2021/12/HEDIS-MY-2022-Measure-Descriptions.pdf. Accessed 4-13-22.

29. https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022#measures. Accessed 4-13-22.

30. Fleming BB, et al. The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic. Diabetes Care. 2001;24(10):1815-20. doi: 10.2337/diacare.24.10.1815.

31. https://diabetesjournals.org/care/article/34/7/1651/38635/Diabetes-Performance-Measures-Current-Status-and . Accessed 4-13-22.

32. Crocker JB, et al. The impact of point-of-care hemoglobin A1c testing on population health-based onsite testing adherence: a primary-care quality improvement study. J Diabetes Sc Technol. 2021;15(3):561-7. doi: 10.1177/1932296820972751.

33. Crocker JB, Lee-Lewandrowsky E, Lewandrowsky N, et al. Implementation of point-of-care testing in an ambulatory practice of an academic medical center. Am J Clin Pathol. 2014;142(5):640-6.

34. Christofides EA, Desai N. Optimal early diagnosis and monitoring of diabetic kidney disease in type 2 diabetes mellitus: addressing the barriers to albuminuria testing. J Prim Care Community Health. 2021;12:21501327211003683. doi: 10.1177/21501327211003683.

35. Schultes B, Emmerich S, Kistler AD, Mecheri B, Schnell O, Rudofsky G. Impact of albumin-to-creatinine ratio point-of-care testing on the diagnosis and management of diabetic kidney disease. J Diabetes Sci Technol. 2021 Oct 28;19322968211054520. doi: 10.1177/19322968211054520.



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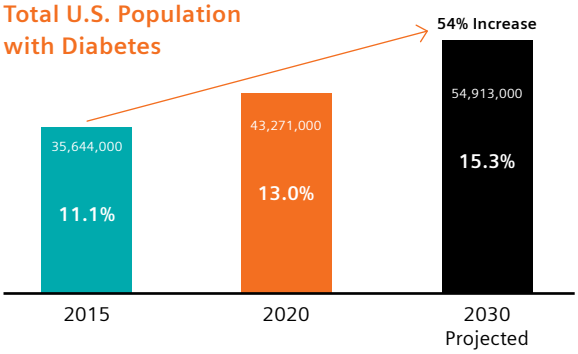


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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.

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A Dream DESTIN-ATION

SANDESTIN GOLF AND BEACH RESORT

BY BRANDI NIMMO



MDescapes



Aria greeted me with a smile on her face and my name on a sign she held in her hand, welcoming me to the panhandle paradise. She would be the driver to my Destin-ation, the beautiful emerald waters and white sand beaches of Destin, Florida. "I hope you don't get a cavity from all the sugar," she coyly offers, "the sugar-like sand we have down here will give you a toothache." She gives me a wink and holds the door as I climb into the black SUV.

As it turned out, there is no exaggeration in comparing the granularity and whiteness of sugar to the snow-white sand on the beaches of the Emerald Coast. The northwest coastline beaches rank at the top in the Continental US, and it's easy to see why. This sand is nearly pure quartz crystal making it ultra-soft, with an almost fluffy-like texture. The color is so white that one needs to wear sunglasses from the glare of brightness. In contrast, rushing up upon it is the emerald-colored ocean. The water rivals any Caribbean island; the color is a gorgeous green, transitioning to an ombre of blues - breathtaking.

I'm new to this neck of the woods, and there are woods. The lush landscape of palm trees sharing space with the pines and live oaks draped in Spanish moss draws me into my surroundings. Nestled among the mature plantings and abundant wildlife and scenery are meandering golf cart and bike paths, walking trails, and streets that stretch from bay to beach and beyond. Sandestin Golf and Beach Resort offers 2400 acres of natural beauty, from the beaches of the Gulf of Mexico over to the shores of the Choctawhatchee Bay and everything in between. A contemporary coastal tower appears, with brickwork, hurricane shutters, and wooden beams, all combine to give the structure a friendly facade. Tucked amongst the trees, Hotel Effie Sandestin is the newly built treasure I'm excited to discover.

This luxury boutique hotel is just a year old and has quickly become the place in Northwest Florida to see and be seen. I'm enthralled as I enter the lobby with the expansive ceilings, fresh floral arrangements, extensive marble, curated artwork, modern crystal fixtures, and design concept. The receptionist offers a craft cocktail or a sweet tea and shares all the complimentary amenities available during my stay as the bellman whisks away my luggage to my room. There's a nice balance of refinement and comfort, sophistication, and Southern hospitality -it's easy to see why this has become a gem of the Emerald Coast.

One thing which intrigues me is the name: The Effie. While walking to my room, I come upon a portrait of the hotel's namesake, Effie Burns, in the main lobby. Below the photograph is a couple of rocking chairs inviting guests to pull up a seat, relax and sit for a spell. Effie was the grandmother to owner and developer Tom Becnel, and she was known for her hospitality and charm, serving as inspiration for what Becnel hopes his hotel will exemplify. The framed picture reminds staff to be exceptional hosts and devoted caretakers. A welcoming emblem to all those entering the property, you are now a part of the family.



The 250-room hotel features multiple configurations, with some being larger suites but all wrapped in comfortable luxury. Design elements from the lobby continue through to the guest rooms with a soothing coastal color palette like the textures and tones of the natural dunes nearby. Pops of rich jewel tones mimic the blues of the sea out the large black paned windows. Lux linens, overstuffed pillows, cozy robes and throw blankets, illuminated mirrors, and organic bath products add to the indulgence.

Spa Lilliana, the onsite procurer of pampering, was a perfect place to begin my stay. The carefully appointed space, with comfortable colors, cocoon-like chaise lounges, and low lighting in the relaxation lounge, sets the tone. There are ten treatment rooms for massage therapists to provide therapeutic and rejuvenating services. I've received many massages in my years, but Mindy performed some magic on my back that I will be forever grateful. Lovely locker rooms, a spa area for manicures, pedicures, salon services, and a boutique with beachwear round out the facility's features. A bit of European indulgence with the Parisian skincare line Biologique Recherche and an organic takeaway from the staff, a gift bottle of Osea Undaria Algae body oil, a sweet reminder of my time at Spa Lilliana.

Exploring the area on higher ground, I venture up to Hotel Effie's Ara Rooftop & Pool Lounge. What a beautiful place to soak in the sun and find respite in one of the cool trellised cabanas. It's a one-of-a-kind experience here, as it's the only rooftop pool in all of Northwest Florida, a popular place to play relaxing games, a giant chessboard and corn hole, or watch the big game on one of the many TVs in the lounge. The spirits are flowing for guests while the DJ spins the beats. As the strung bistro lights come on and the mood softens at dusk, it's a gorgeous setting to take in the 360-degree panoramic views and watch the sunset. And for a family affair, a weekly movie night by the pool for the little ones - Kung Fu Panda under the moonlight, is a memory maker.

The resort provides a free shuttle to deliver guests to the many popular points in the area; my Destin-ation is a day at the touted beach. It's a short distance where I'm dropped off at the private beach area, greeted by Hotel Effie staff, who set up a beach chair, towels, and umbrella and offer a menu for lite bites and snacks. Everything was perfect with the sound of the waves and the infamous sugar sand between my toes; my only worry would be if the tide would reach my chair. Thanks to the palm trees, emerald sea, and Florida sun, all my stress evaporated. A perfect day in the panhandle.

The Sandestin Golf and Beach Resort has many places to eat, but it's nice to have a lovely place to dine onsite at the Hotel Effie. Ovide, the signature restaurant, lovingly named after Effie's husband, is not only convenient - it's cool. The space features significant floral art displayed overhead for dramatic effect, a spacious bar accented with mirrors, and large windows to allow the light to stream in, balancing the dark interior



palate. The interior design is equally laudable with the culinary craftmanship courtesy of celebrity chef Hugh Acheson. Chef Acheson combines the local flavors of the Gulf region, enhancing them with French cooking flare. He is a James Beard Award winner, served as a judge on Top Chef, and is the chef/owner of several top restaurants in the South. Acheson and his team have developed heightened cuisine offerings that make Ovide an exceptional eatery.

Sweetbay Coffee is your best bet for grab-and-go sandwiches, pastries, and barista favorites. A search for easy fare, small plates, and creative craft cocktails, pull up a seat to The Lobby Bar. One of the best salads I've ever enjoyed was on the light menu at the Ara Rooftop & Lounge. But when you venture out of the Hotel Effie, the Village at Baytowne Wharf is just a stone's throw away. The 28-acre waterfront town center is a unique collection of award-winning restaurants, specialty merchants, lively nightclubs, and charming boutiques. A jam-packed calendar with special events and fun festivals makes this the premier gathering spot for guests and residents of Sandestin.

This coastal community has made magical memories for its guests and generations of families for over 45 years, offering every imaginable amenity for visitors to enjoy. Golf: Four top-notch courses, The Raven is a Robert Trent Jones Jr. tract, and Golf Magazine dubs the Burnt Pine course as the "Crown Jewel of Florida Golf." Whether it is 18 holes from the beach to the bay or individual instruction from the pros, pure enjoyment is par for these courses. Fitness: a state-of-the-art gym with a wide variety of cardio equipment options and a long list of classes to join in like yoga, turbo kick, and Zumba, to name a few. Tennis: 12 world-class HydroGrid clay and three hard tennis courts, six Pickleball courts with private lessons with pros, fun Round Robin tournaments, and ball machines. Fishing: Destin was discovered and settled by fishermen in 1835, and it's known for being "The World's Luckiest Fishing Village." Charters, overnight fishing trips, and equipment are available at the Baytowne Marina. Water sports: Waverunners, pontoon boats, kayaks, boogie, and paddleboards are a great way to enjoy the Gulf waters. Featured activities that children young and old can enjoy: Floating Water Park, beach bonfires, Baytowne Adventure Zone with zip line, ropes course and tower climb, Blast Arcade and Laser Maze, bicycles, nature trails, treehouse, and carousel are all available for free or a nominal fee.

Once you arrive, you never have to get into your vehicle because the Hotel Effie is a self-inclusive world, complete in itself, in that everything you need is right on the Sandestin Golf and Beach Resort property. With the warm hospitality and charm of the South, with so many entertainment activities, and all the opportunities for relaxation and rejuvenation, this dream Destin-ation is one you may never wish to leave.



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Introducing the next generation in point-of-care diagnostics. With a growing menu of tests, LumiraDx uses a simple process that allows for more time with your patients by using microfluidic technology that delivers results in minutes. Learn more about rapid COVID-19 diagnostic solutions for your physician office at LumiraDx.com.

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BIOFIRE® RESPIRATORY 2.1-EZ (RP2.1-EZ)1 PANEL (EUA)1

From BioFire

SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. In your clinic, you can test for 19 common respiratory pathogens, including SARS- CoV-2, with the BioFire RP2.1-EZ Panel (EUA)[1]—now available under an FDA Emergency Use Authorization. Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects.

1. This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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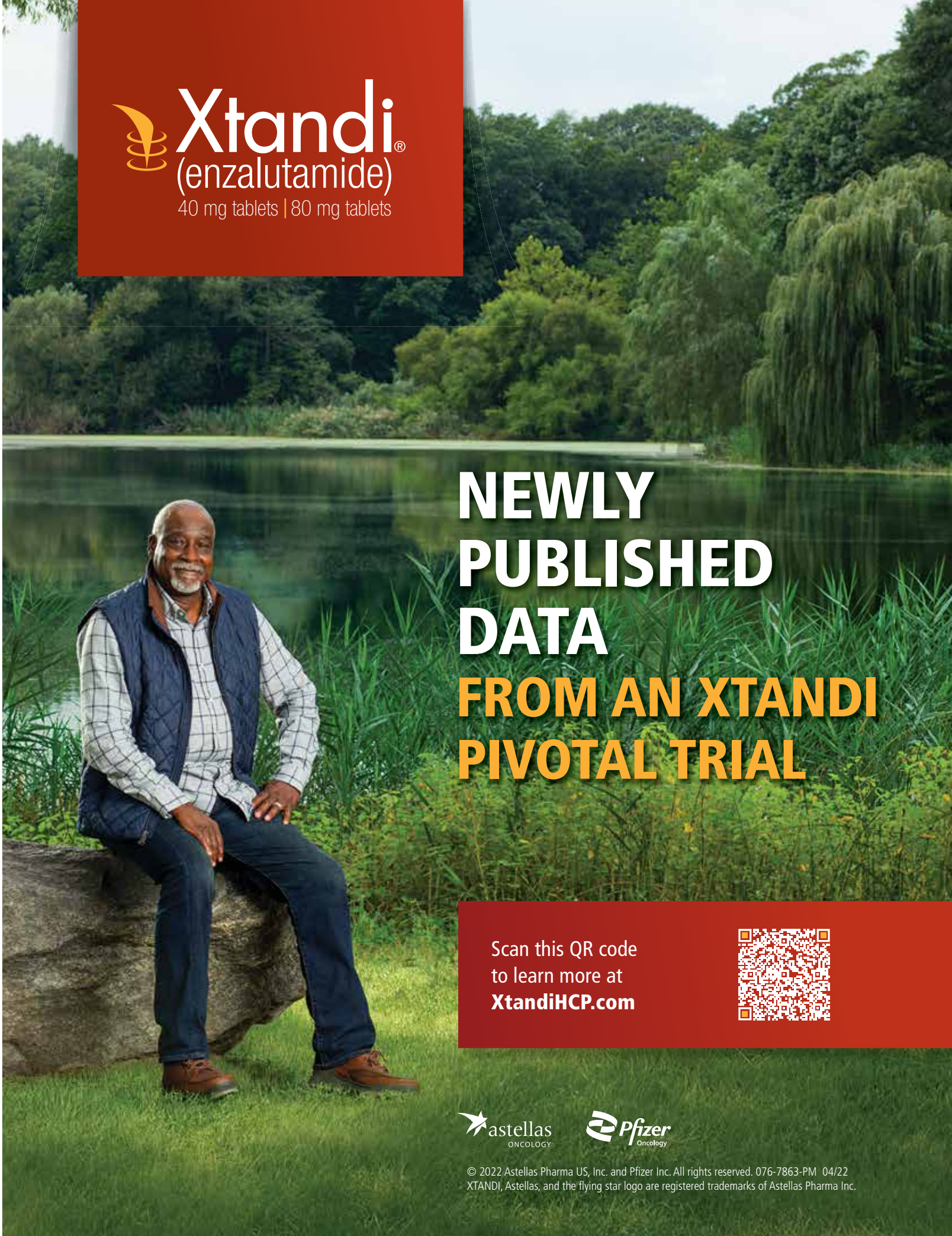


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COMPREHENSIVE IN-OFFICE DIABETES TESTING WITH THE DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes with CLIA-waived HbA1c testing and ACR[1] ratio. Improve patient experience and overall outcome by providing actionable results in minutes.

1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

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LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

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ACCURATE, ACTIONABLE RESULTS FROM THE LEADER IN POINT-OF-CARE LIPID TESTING

From Abbott

The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.

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3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing 1614

- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- **Reimburses using 6 CPT codes, National Average = $750 - $1000 per test**
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing

(can be combined with SUDOMOTOR into 1 full system)

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- **Reimburses $170/test using 3 CPT codes**
- Provides a 1 page summary up to a full 24 page comprehensive report

1616



3 SudoMotor Testing 1615

(can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- **Reimburses $130/test (national average)**

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From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

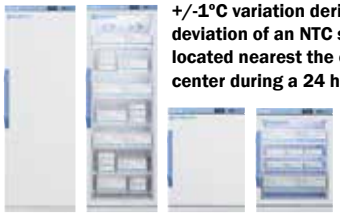
- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

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1620

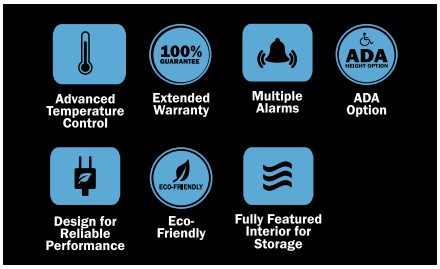
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Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

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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	**936.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**949.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**1,059.50**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**1,072.50**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**1,180.40**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,193.40**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,497.60**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,510.60**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**2,002.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**2,015.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**2,294.50**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**2,307.50**

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	**2,762.50**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**3,113.50**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,413.50**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,771.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**3,178.50**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**5,063.50**

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

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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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TOXICOLOGY SCREENING SIMPLIFIED ABBOTT'S IMMTOX 270 BENCHTOP ANALYZER NOW WITH 14 ASSAYS CLIA CATEGORIZED AS MODERATE COMPLEXITY

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The ImmTox270 benchtop analyzer offers comprehensive toxicology screening solutions for physician offices, treatment centers and independent laboratories.

Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

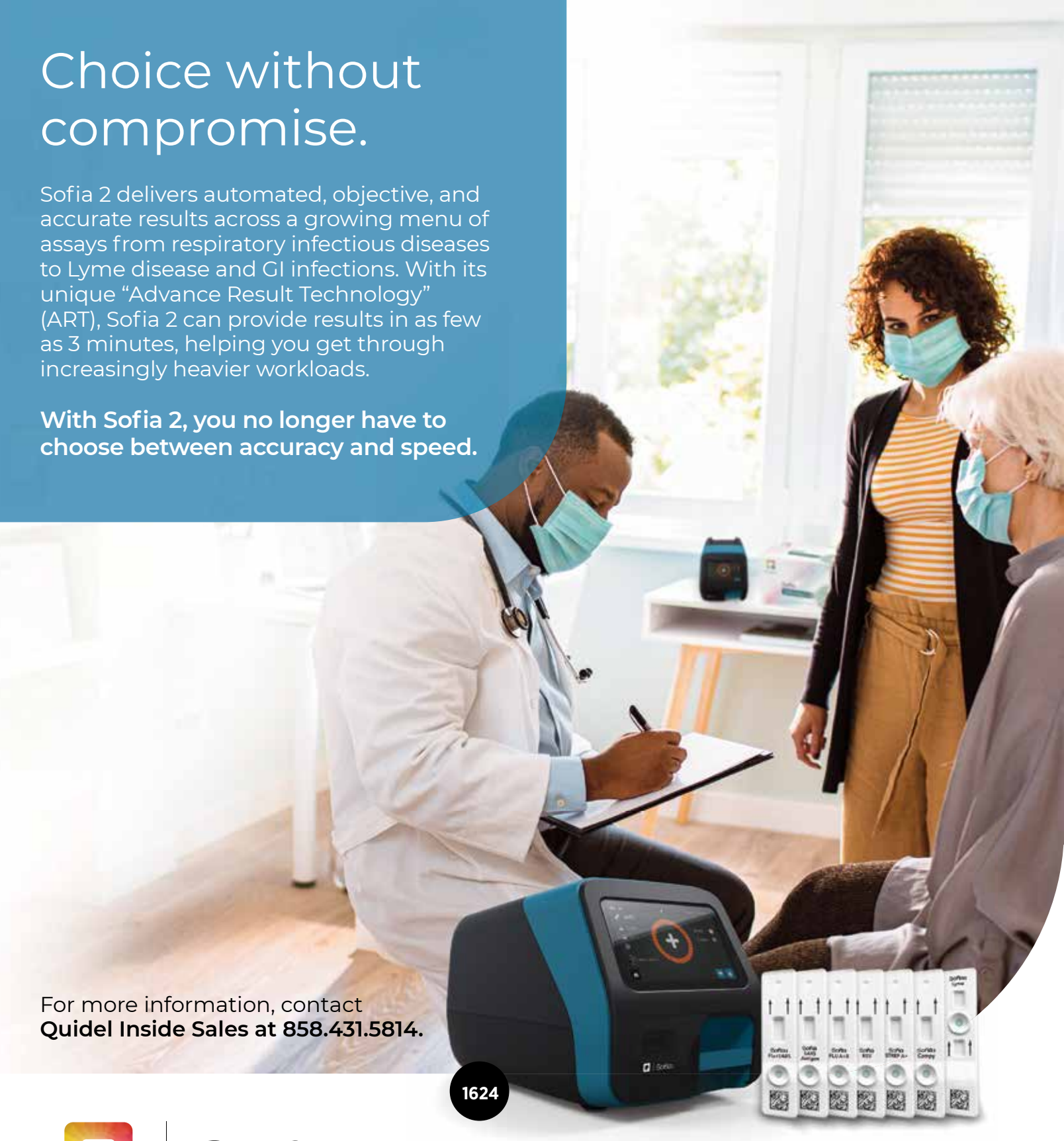
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Choice without compromise.

Sofia 2 delivers automated, objective, and accurate results across a growing menu of assays from respiratory infectious diseases to Lyme disease and GI infections. With its unique “Advance Result Technology” (ART), Sofia 2 can provide results in as few as 3 minutes, helping you get through increasingly heavier workloads.

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AD10102100EN00 (03/22)



OSOM® BVBLUE®

From Sekisui Diagnostics

The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

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OSOM® TRICHOMONAS RAPID TEST

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The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis antigens from vaginal swabs or from the saline solution. The OSOM® Trichomonas Rapid Test is a CLIA-waived rapid test available today. OSOM® Trichomonas is more sensitive than wet mount due to the assay being able to detect viable and non-viable organisms which offers significant benefits to the patient and clinician alike.

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ULTRA HCG COMBO TEST

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The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test does not have a false negative result from hCG variants providing physicians with a higher level of confidence.

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

A FIRST-LINE TREATMENT OPTION IN ADVANCED NSCLC

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]**

NCCN Guidelines® for Non-Small Cell Lung Cancer recommend cemiplimab-rwlc (LIBTAYO) as a Category 1* (preferred) systemic therapy option for advanced NSCLC[2†]

NCCN PREFERRED CATEGORY 1* OPTION FOR ADVANCED NSCLC[2]

Category 1* (preferred) recommendation[2]

PD-L1–POSITIVE (≥50%) ADVANCED NSCLC
A preferred PD-1 inhibitor[2]

Negative for actionable molecular markers and no contraindications to PD-1 or PD-L1 inhibitors[2]

***Category 1 recommendation is based upon high-level evidence and uniform NCCN consensus that the intervention is appropriate.[2]**

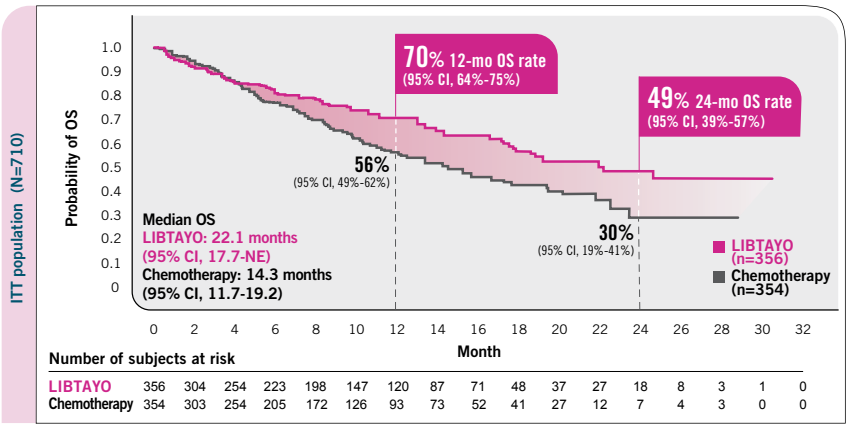
†See the NCCN Guidelines for the detailed recommendations, including other preferred options.

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way.

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor; NCCN=National Comprehensive Cancer Network; PD-1=programmed death receptor-1; PD-L1=programmed death ligand 1; ROS1=ROS proto-oncogene 1, receptor tyrosine kinase.

Approved in patients with advanced NSCLC‡ with PD-L1 ≥50% and no EGFR, ALK, or ROS1 aberrations[1]

LIBTAYO significantly EXTENDED SURVIVAL vs platinum-based chemotherapy in EMPOWER-Lung 1[1,3]



32%
Reduction in risk of death HR=0.68
(95% CI, 0.53-0.87)
P=0.0022

Median OS: 22.1 months
(95% CI, 17.7-NE) with LIBTAYO vs 14.3 months (95% CI, 11.7-19.2) with chemotherapy[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]
- **Nearly 3 out of 4 patients (74%)** who progressed on platinum-based chemotherapy crossed over to LIBTAYO treatment[1]

‡Patients with locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation or who have metastatic NSCLC.[1]

HR=hazard ratio; NE=not evaluable; OS=overall survival.

Study design

EMPOWER-Lung 1 was a large, phase 3, randomized, open-label, multicenter study that included patients with locally advanced NSCLC who were not candidates for treatment with definitive concurrent chemoradiation or patients with stage IV disease who received no prior systemic treatment for recurrent or metastatic NSCLC. Key eligibility criteria included PD-L1 expression ≥50% and ECOG PS 0 or 1. Patients with type 1 diabetes mellitus or hypothyroidism only requiring hormone replacement were eligible. Patients with brain metastases that were treated and clinically stable (neurologically returned to baseline) for at least 2 weeks prior to randomization were permitted. Radiological confirmation of stability or response was not required. Patients were excluded if they had EGFR, ALK, or ROS1 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.[1,3,4]

Patients were randomized 1:1 to receive LIBTAYO 350 mg IV Q3W for up to 108 weeks or investigator's choice of the following platinum-doublet chemotherapy regimens for 4 to 6 cycles: paclitaxel + cisplatin or carboplatin; gemcitabine + cisplatin or carboplatin; or pemetrexed + cisplatin or carboplatin followed by optional pemetrexed maintenance in patients with nonsquamous histology. Treatment with LIBTAYO continued until RECIST 1.1-defined progressive disease, unacceptable toxicity, or for up to 108 weeks. 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 progression was observed. Patients who experienced IRC-assessed RECIST 1.1-defined progressive disease on chemotherapy were permitted to receive treatment with LIBTAYO monotherapy until further progression, unacceptable toxicity, or for up to 108 weeks.[1,3]

The primary efficacy endpoints were OS and PFS. Secondary endpoints included ORR (key), DOR, and safety and tolerability.[1,4]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

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

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.

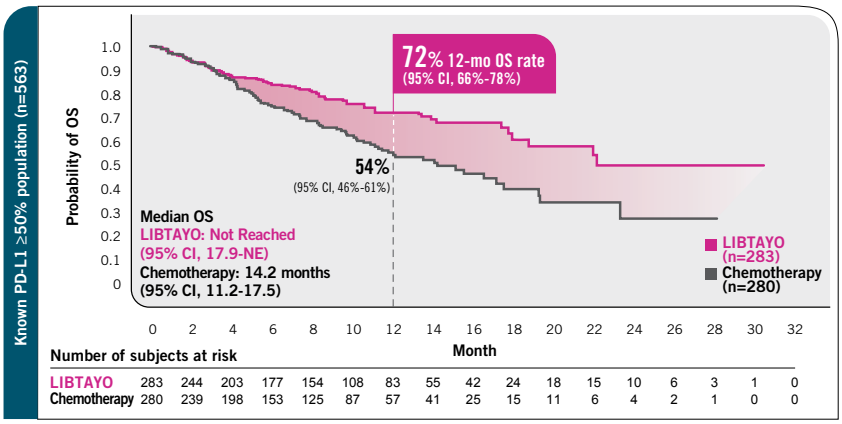
Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

The EMPOWER-Lung 1 study was designed to enroll patients with PD-L1 ≥50%.[4]

- 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[4]
- 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[4] (LIBTAYO is not indicated in patients with <50% PD-L1 expression)

In an analysis of the subset of patients with advanced NSCLC* who had no EGFR, ALK, or ROS1 aberrations and known PD-L1 ≥50% (n=563):

Overall survival with LIBTAYO vs platinum-based chemotherapy in EMPOWER-Lung 1[3-5]



43% Reduction in risk of death HR=0.57
(95% CI, 0.42-0.77)
P=0.0002

Median OS: Not Reached
(95% CI, 17.9-NE) with LIBTAYO vs 14.2 months (95% CI, 11.2-17.5) with chemotherapy[4,5]

- Number of deaths: 25% of patients (70 out of 283 patients) with LIBTAYO and 38% of patients (105 out of 280 patients) with chemotherapy[4,5]
- **72% of patients** who progressed on platinum-based chemotherapy crossed over to LIBTAYO treatment[6]

Adapted with permission from Sezer et al, *Lancet* 2021.[4]

***Patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation or who had metastatic NSCLC.[4]**

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 (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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. 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.

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.

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

For more information,
scan this QR code with your phone, or visit **LIBTAYOhcp.com/NSCLC**

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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

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

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 dermatologic adverse reactions (continued): 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.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.5.2021.* © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed June 16, 2021. To view the most recent and complete version of the guidelines, go online to NCCN.org. **3.** 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)(suppl):1-178. **4.** 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. **5.** PD-L1 IHC 22C3 pharmDx [instructions for use]. Carpinteria, CA: Dako, Agilent Pathology Solutions; 2021. **6.** Data on file. Regeneron Pharmaceuticals, Inc.

REGENERON | SANOFI GENZYME

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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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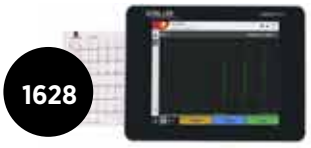
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WHY NO ONE RESPONDS TO "WHY DID YOU WANT TO BECOME A DOCTOR?" WITH ANYTHING STARTING WITH "THE SALARY —"

BY MIRIAM SWEENEY





Money is one of the most influential things in our lives that is simultaneously most difficult to talk about. And the medical field is no exception. In my unique situation, I've had the opportunity to talk with an abnormally high number of doctors-to-be about their finances.

It started when I began to edit friends' personal statements with them before their applications to medical school. Editing one friend's statement led to editing their friend's statement, and soon enough, I had a small seasonal editing side gig on my hands.

As I worked with premeds to articulate why they wanted to go to medical school, it surprised me how infrequently people would tell me that one of their motivations for going to medical school was financial. When talking with bright young people who are midway through their undergraduate degrees and sincerely contemplating the next decade of their lives and stating (not only with a straight face, but with excessive volunteer and shadowing hours and effort to get great grades) that they think that going back to school and staying in it for years to come is actually a fantastic idea, very few talked me about how much money they hope to make.

In fact, as part of my personal statement editing process, I'll ask everyone why they want to go to med school. I never let them give me just one simple answer. I encouraged everyone I worked with to brainstorm a list of responses in the style of "there are no wrong answers here." Of course, I didn't tell them they needed or even should include all the reasons in their personal statement, but I wanted to see their minds were open and they were willing to be honest with themselves. And not one of the dozens of students who I worked with ever mentioned compensation until after I prodded them and indicated that money and lifestyle are also valid reasons for enormous career decisions. Once prompted, everyone would chuckle, loosen up a bit, and agree that they wanted to be compensated well for hard work in their career.

But we don't talk about this. We don't talk about how much money we make or how much money we wish we made. Or, if we do, perhaps we fear being lumped together with money-hungry ladder climbing go-getters who want nothing more than to increase their salary and die someday on a king-sized bed built of hundred dollar bills. No one wants to be lumped into a category with that guy.

But that stigma is keeping us from conversations that could potentially truly benefit us and help us in continuing our education of how to navigate the world as professionals, providers, family members, members of various communities, and adults in general.

When exploring the need for a physician personal finance education platform, I had as many conversations with medical students, residents, and early-in-their-attending-years physicians as I could. I want to know the same thing from all of them: I wanted to better understand their experience and relationship with money and how those have shaped their decisions and experiences in relation to their careers. In a field as demanding and highly intellectual as medicine, I was surprised by the enormous variety I found when people talked through their relationship with money. Some people I talked to were extremely debt-tolerant, going into more debt than strictly necessary to ensure that their undergraduate medical school and residency experiences were not just livable, but top-notch. Others had been raised in families where they were taught that maintaining a monthly

balance on their credit cards would improve their credit scores (in case you fall into this category, know that it doesn't). Still others would readily confess (and sometimes proudly brandish) their utter and complete ignorance to all things financial — whether we were discussing simple monthly budgets or complex investing and retirement plans — and wave to me in the direction of a significant other, a cousin, or, in many cases, a tired and caring member of their physician faculty who had somehow earned himself or herself the reputation for being the go-to money person on staff for generations of medical students, residents, and attending physicians.

In stages as demanding and vertical as medical school and residency, it is a blessing, I'm sure, to have someone in your life who is willing to take on the mental load of finances. In fact, in my informal research, I discovered it was more common than not for a medical student's partner to be not just in charge of household finances, but the primary go to person for matters of their own educational debt and repayment. In other words, we find ourselves with a system that is not only so demanding and rigorous that it's leading to increasingly poor health outcomes for its own people, but that it leaves individuals so flabbergasted as to how to navigate its financial implications that those individuals are left to resort to the patient research of their loved ones to understand their own options for how to pay for their medical education.

Such a system, combined with the trend of not talking about finance, also creates an uncomfortable inequality between professionals. According to recent statistics, 25% of medical students graduate without debt from medical school. That means that if you as a medical student are looking to your peers for an example of what a suitable, sustainable lifestyle is like for yourself, then a quarter of the time, you may be looking at someone who is not dealing with the mental load and pressure of debt in the way you are dealing with it. Even something as simple as seeing your friends take vacations or make arguably unnecessary purchases may create subliminal pressure for you to also indulge in things that appear to be affordable for a fellow medical student, whether or not you have determined that they are personally affordable for you.

This tendency to avoid discussing personal finances has also led to extreme oversimplification from a systemic perspective. I was again surprised in my conversations with medical students and residents to hear how generally unhelpful many of their interactions with their financial aid offices at their respective institutions have been. One person recounted being told (for the entirety of a lecture, mind you, that was advertised as designed to help them to make a plan for budgeting on a limited residence budget) that their financial situation was their fault because their generation was likely to be buying fancy coffee daily instead of brewing their own. Such oversimplification and condescension was, I'm sorry to say, much more common than one would hope in these conversations with medical students, residents, and attending physicians. Such an experience, even this one in its extreme, produces droplets of shame that are bound to fester and prevent otherwise productive conversations, whether formal or spontaneous, from happening in the first place. It could prevent an individual physician from learning something about money management or investing that could change their lives – and, by extension, the lives of their patients and families – for the better.

For most people, it is unthinkable to get through a full medical education without any debt. And that's not necessarily a bad thing; modern society allows for investments of time and money into the promise of future value, and the existence of student loans is one of the things helping to ensure that we have the best providers being trained and not just the providers who happen to come from families who can afford to make them doctors. But if we don't reevaluate our own relationship with money and openly revisit the stigma of talking about money and one another, I'm afraid that we will create a stagnant environment where needed change – whether that change is needed on administrative levels to ensure the sustainability and financial viability of healthcare organizations, or needed on individual levels to sustain and promote good mental health for hard-working physicians– is entirely inaccessible.

You can start today. If you have a solid knowledge of personal finance, complete with a robust retirement and investing plan and debt payoff strategies, then bring up something you've learned or heard recently about personal finance with your colleagues. If they see you're willing to discuss finances, they may also be willing to open up.

Conversely, if you don't feel confident in your own understanding of your options and personal finances — or even if you just recognize that there's no way to know what you don't know — then make a plan to learn something. There are plenty of podcasts and Youtubers who discuss personal finance at length, and some of us even focus specifically on physician personal finance. If you want a bite sized, free way to start that educational experience, I would love to hear if the app that my team and I built in response to those dozens of conversations I had scratches that itch for you.

What is perhaps most important is remembering that money is just a tool. If we treat it like a tool and not like a prize to be won on one end of the spectrum or an unknown, unfeeling god to fear on the other, then we'll be more likely to be personally in control of our money. We'll be more able to be a source of positive change where changes are needed to make the world safer, healthier, and more prone to thrive.

1. *MedSchoolInsiders: https://medschoolinsiders.com/premed/the-real-cost-of-medical-school/#:~:text=Approximately%2012%25%20graduate%20with%20%24300%2C000,just%20a%20few%20years%20ago.*

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