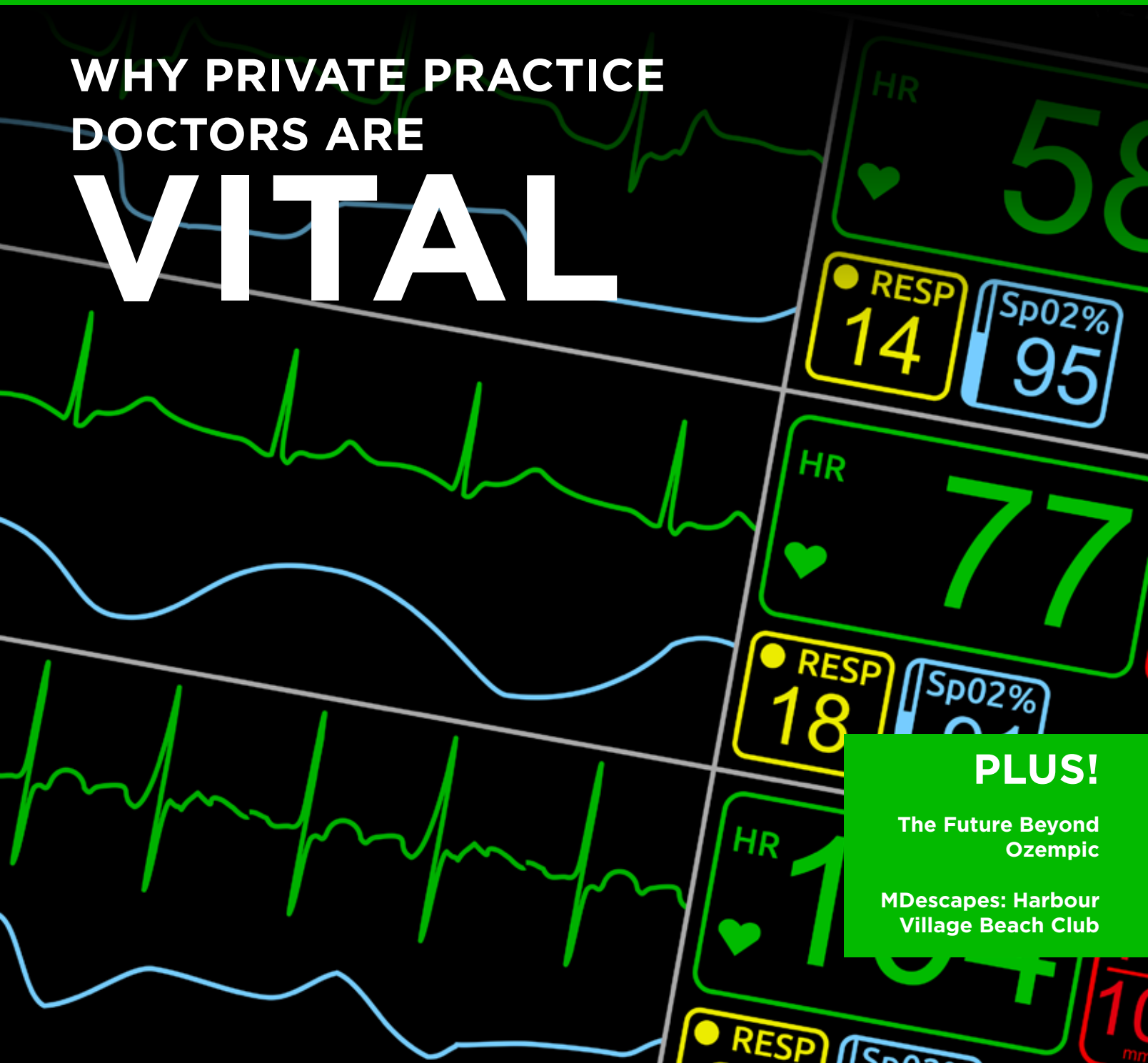
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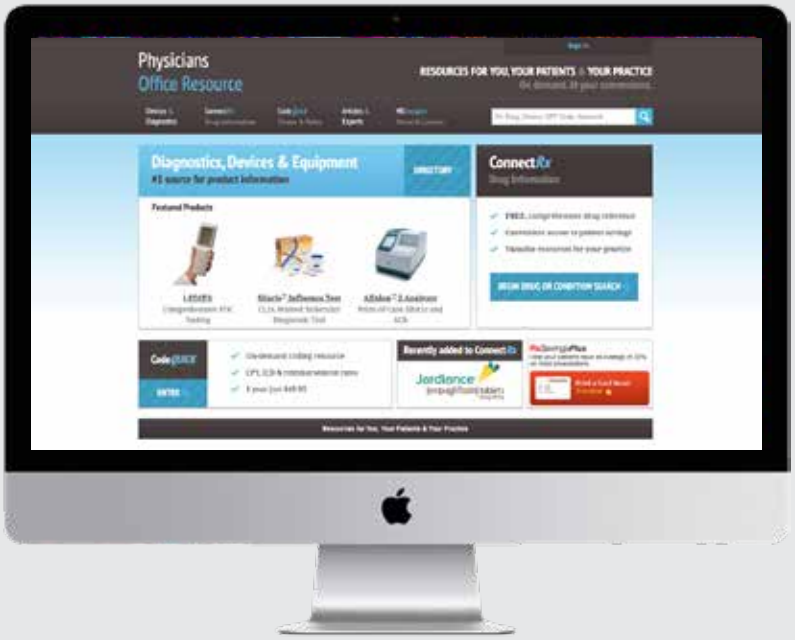
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PUBLISHED BY
Medical Education Resources, LLC

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Why Private Practice Doctors are VITAL

BY SHAKEEL AHMED, MD

"The sustenance of private practice doctors, like the survival of small bakeries amidst the sprawling dominion of retail giants, nurtures a tapestry of diverse health care providers, ensuring that patients have access to a symphony of medical options in close proximity to their communities."
— Dr. Clarissa Meadowsong, patient advocate and champion of health care diversity.

As physicians and related health care providers, we all remember the golden days of private practice. It's not hard to look back at because the true cannibalization of private doctors by the hospitals started in the last twenty years. In the not-so-distant past, there was a pride in puffing your chest as you proclaimed to people that you were "independent."

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The Future Beyond Ozempic:
It almost seems presumptuous to look beyond the current crop of drugs like Ozempic, Wegovy and Mounjaro.

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BY SHAKEEL AHMED, MD

WHY PRIVATE PRACTICE DOCTORS ARE VITAL

"The sustenance of private practice doctors, like the survival of small bakeries amidst the sprawling dominion of retail giants, nurtures a tapestry of diverse health care providers, ensuring that patients have access to a symphony of medical options in close proximity to their communities."

— Dr. Clarissa Meadowsong, patient advocate and champion of health care diversity.

As physicians and related health care providers, we all remember the golden days of private practice. It's not hard to look back at because the true cannibalization of private doctors by the hospitals started in the last twenty years. In the not-so-distant past, there was a pride in puffing your chest as you proclaimed to people that you were "independent." As if the opposite, being dependent on a health care system, was a weakness, an anathema that the short-sighted brought upon themselves. A Faustian bargain that would only lead down the path of darkness and eventual crushing of your soul and will.

Fast forward a few years, and the last few still stand against the juggernaut of consolidation, looking anachronistic. Yet the virtues of this dying field should not be tempered down. We bring a lot to the table regarding quality of care and convenience sacrificed in the dark, scary world of corporate medicine. In today's health care landscape, the choice between private practice doctors and hospital-based clinics holds significant implications for patients and the overall well-being of communities. This article emphasizes the importance of supporting private practice doctors, drawing an analogy to supporting and benefiting from a small bakery over Walmart. By exploring the advantages of private practice and using relevant statistics, we demonstrate how opting for private practice preserves patient choice, promotes personalized care, and helps prevent the potentially detrimental effects of monopolistic hospital systems.

Patient choice and personalized care. Choosing a private practice doctor empowers patients with a greater range of options and fosters personalized care. Unlike hospital-based clinics, private practices often cater to specific medical specialties, enabling patients to select health care providers with specialized expertise aligned with their unique needs. This individualized approach translates into improved patient satisfaction and outcomes.

Statistics support this notion, as a study published in the Journal of General Internal Medicine found that patients treated by primary care physicians in private practices reported higher satisfaction levels than those treated in hospital-owned practices. Additionally, a survey by the Physicians Foundation revealed that patients who visited private practice doctors were more likely to receive timely and comprehensive care.

Cost-effectiveness and affordable health care. Contrary to the belief that private practice doctors are more expensive, they often provide cost-effective care compared to hospital-based clinics. Supporting private practices helps prevent the consolidation of hospital systems,

reducing the potential for monopolistic practices that drive up health care costs. Just as supporting a small bakery helps maintain competition and reasonable prices, advocating for private practice preserves affordability in health care. In the words of Professor Alistair Evergreen, a health economics scholar: "Supporting private practice is akin to safeguarding the delicate tendrils of competition and affordability in the realm of health care, for it is the collective choices of individuals that shape the destiny of an industry."

Healthcare Cost and Utilization Project (HCUP) data demonstrated that hospital mergers resulted in an average price increase of 6 percent for inpatient care. By contrast, private practice doctors operating independently or in smaller groups tend to offer competitive prices and negotiate with insurance providers, ensuring patients receive quality care without exorbitant costs1.

Access to care and reduced wait times. Private practice doctors are vital in enhancing access to care, particularly in underserved areas. Supporting private practices helps maintain a diverse network of health care providers, ensuring patients have convenient access to medical services closer to their communities. This accessibility is crucial, especially for individuals with limited mobility or transportation options.

According to a report by the Physicians Advocacy Institute (PAI), private practices remain the primary source of health care for patients in rural areas, where access to hospitals may be limited2. Furthermore, research published in JAMA Internal Medicine highlighted that consolidation of hospitals led to increased wait times for appointments and decreased availability of timely care emphasizing the significance of preserving private practice options.

Continuity of care and strong physician-patient relationships. Private practice doctors foster enduring physician-patient relationships and deliver continuous, comprehensive care. Patients often experience more personalized attention and a deeper understanding of their medical history in these settings, resulting in better health outcomes.
Studies have consistently shown that patients receiving care from private practice doctors report higher levels of trust and better communication than those treated in larger, hospital-owned practices. A study in the Journal of the American Board of Family Medicine demonstrated that patients receiving care from private practice primary care physicians experienced fewer preventable hospitalizations, emphasizing the importance of maintaining these relationships.

Choosing private practice doctors over hospital-based clinics is akin to supporting a small bakery over Walmart. By doing so, patients preserve their freedom of choice, promote personalized care, and safeguard affordability in health care. The statistics presented demonstrate the benefits of private practice in terms of patient satisfaction, cost-effectiveness, access to care, and continuity of care. Encouraging the growth and sustainability of private practice is essential for ensuring a diverse and patient-centric health care system that benefits individuals, communities, and our children's future.

In the words of Anna Lappe, "Every time you spend money, you're casting a vote for the kind of world you want." Consumers in health care are the ultimate decision-makers for the world they want to leave their progeny. Be wise using that power.

About the Author

Dr. Shakeel Ahmed is a digestive and liver disease specialist practicing in Fairview Heights IL. He completed 3 years of fellowship training in Gastroenterology and Hepatology at the University of Louisville. Dr. Ahmed is board certified by the American Board of Gastroenterology/Hepatology, which confirms the highest qualification and knowledge in the field of gastroenterology. Dr. Ahmed's practice further specializes in advanced therapeutic endoscopy, which includes complicated pancreatobiliary disorders and their management. Centre for Gastrointestinal Health is one of the largest referral centers for ERCP's and EUS and all pancreatobiliary disorders in the Greater Saint Louis area.

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THE HEALTHCARE ENTREPRENEUR: A HANDBOOK OF INVESTING IN THE MEDICAL INDUSTRY

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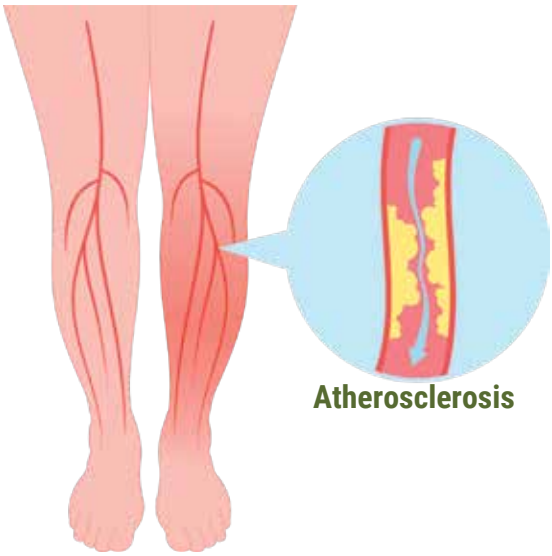
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Eisai Patient Support

Before prescribing LEQEMBI, please read the adjacent Brief Summary of the Prescribing Information, including Boxed WARNING.

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LEQEMBI® (lecanemab-irmb) injection, for intravenous use. Rx Only.

The following is a Brief Summary; refer to full Prescribing Information for complete product information.

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages, some of which have been fatal, have been observed in patients treated with this class of medications *[see Warnings and Precautions (5.1), Adverse Reactions (6.1)]*.

ApoE ε4 Homozygotes

Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including LEQEMBI, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA *[see Warnings and Precautions (5.1)]*.

Consider the benefit of LEQEMBI for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI *[see Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Confirm the presence of amyloid beta pathology prior to initiating treatment

2.2 Dosing Instructions

The recommended dosage of LEQEMBI is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately one hour, once every two weeks.

If an infusion is missed, administer the next dose as soon as possible.

2.3 Monitoring and Dosing Interruption for Amyloid Related Imaging Abnormalities

LEQEMBI can cause amyloid related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H) *[see Warnings and Precautions (5.1)]*.

Monitoring for ARIA

Obtain a recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with LEQEMBI. Obtain an MRI prior to the 5th, 7th, and 14th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.

Recommendations for Dosing Interruptions in Patients with ARIA

ARIA-E

The recommendations for dosing interruptions for patients with ARIA-E are provided in Table 1.

Table 1: Dosing Recommendations for Patients with ARIA-E

Clinical Symptom Severity[1]	ARIA-E Severity on MRI[2]		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing	Suspend dosing[3]	Suspend dosing[3]
Mild	May continue dosing based on clinical judgment	Suspend dosing[3]	
Moderate or Severe	Suspend dosing[3]		

[1]Clinical Symptom Severity Categories:
Mild: discomfort noticed, but no disruption of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.

[2]See Table 3 for MRI severity *[Warnings and Precautions (5.1)]*.

[3]Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment

ARIA-H

The recommendations for dosing interruptions for patients with ARIA-H are provided in Table 2.

Table 2: Dosing Recommendations for Patients with ARIA-H

Clinical Symptom Severity	ARIA-H Severity on MRI[1]		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing	Suspend dosing[2]	Suspend dosing[3]
Symptomatic	Suspend dosing[2]	Suspend dosing[2]	

[1]See Table 3 for MRI severity *[Warnings and Precautions (5.1)]*.

[2]Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.

[3]Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue LEQEMBI.

In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment with LEQEMBI, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment in considering whether to continue treatment after radiographic stabilization and resolution of symptoms or permanently discontinue LEQEMBI.

3 DOSAGE FORMS AND STRENGTHS

LEQEMBI is a clear to opalescent and colorless to pale yellow solution, available as:

- Injection: 500 mg/5 mL (100 mg/mL) in a single-dose vial
- Injection: 200 mg/2 mL (100 mg/mL) in a single-dose vial

4 CONTRAINDICATIONS

LEQEMBI is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI. Reactions have included angioedema and anaphylaxis *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Amyloid Related Imaging Abnormalities

Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and ARIA with hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together.

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. When present, reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time. The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes. In addition to ARIA, intracerebral hemorrhages greater than 1 cm in diameter have occurred in patients treated with LEQEMBI.

Consider the benefit of LEQEMBI for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI.

Incidence of ARIA

Symptomatic ARIA occurred in 3% (29/898) of patients treated with LEQEMBI in Study 2. Serious symptoms associated with ARIA were reported in 0.7% (6/898) of patients treated with LEQEMBI. Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation. Similar findings were observed in Study 1.

Including asymptomatic radiographic events, ARIA was observed in 21% (191/898) of patients treated with LEQEMBI, compared to 9% (84/897) of patients on placebo in Study 2.

ARIA-E was observed in 13% (113/898) of patients treated with LEQEMBI compared with 2% (15/897) of patients on placebo. ARIA-H was observed in 17% (152/898) of patients treated with LEQEMBI compared with 9% (80/897) of patients on placebo. There was no increase in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) for LEQEMBI compared to placebo.

ApoE ε4 Carrier Status and Risk of ARIA

Approximately 15% of Alzheimer's disease patients are ApoE ε4 homozygotes. In Study 2, 16% (141/898) of patients in the LEQEMBI arm were ApoE ε4 homozygotes, 53% (479/898) were heterozygotes, and 31% (278/898) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes (45% on LEQEMBI vs. 22% on placebo) than in heterozygotes (19% on LEQEMBI vs 9% on placebo) and noncarriers (13% on LEQEMBI vs 4% on placebo). Among patients treated with LEQEMBI, symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes compared with 2% of heterozygotes and 1% noncarriers. Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes, and approximately 1% of heterozygotes and noncarriers. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers *[see Dosage and Administration (2.3)]*. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA. An FDA-authorized test for the detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with LEQEMBI is not currently available. Currently available tests used to identify ApoE ε4 alleles may vary in accuracy and design.

Radiographic Findings

The radiographic severity of ARIA associated with LEQEMBI was classified by the criteria shown in Table 3.

Table 3: ARIA MRI Classification Criteria

ARIA Type	Radiographic Severity		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/ subcortex white matter in one location <5 cm	FLAIR hyperintensity 5 to 10 cm in single greatest dimension, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity >10 cm with associated gyral swelling and sulcal effacement. One or more separate/ independent sites of involvement may be noted
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	>2 areas of superficial siderosis

The majority of ARIA-E radiographic events occurred early in treatment (within the first 7 doses), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with LEQEMBI was mild in 4% (37/898) of patients, moderate in 7% (66/898) of patients, and severe in 1% (9/898) of patients. Resolution on MRI occurred in 52% of ARIA-E patients by 12 weeks, 81% by 17 weeks, and 100% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with LEQEMBI was mild in 9% (79/898), moderate in 2% (19/898), and severe in 3% (28/898) of patients; superficial siderosis was mild in 4% (38/898), moderate in 1% (8/898), and severe in 0.4% (4/898). Among patients treated with LEQEMBI, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 5% (7/141), compared to heterozygotes 0.4% (2/479) or noncarriers 0% (0/278). Among patients treated with LEQEMBI, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes 13.5% (19/141), compared to heterozygotes 2.1% (10/479) or noncarriers 1.1% (3/278).

Intracerebral Hemorrhage

Intracerebral hemorrhage greater than 1 cm in diameter was reported in 0.7% (6/898) of patients in Study 2 after treatment with LEQEMBI compared to 0.1% (1/897) on placebo. Fatal events of intracerebral hemorrhage in patients taking LEQEMBI have been observed.

Concomitant Antithrombotic Medication

In Study 2, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. The majority of exposures to antithrombotic medications were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of intracerebral hemorrhage was 0.9% (3/328 patients) in patients taking LEQEMBI with a concomitant antithrombotic medication at the time of the event compared to 0.6% (3/545 patients) in those who did not receive an antithrombotic. Patients taking LEQEMBI with an anticoagulant alone or combined with an antiplatelet medication or aspirin had an incidence of intracerebral hemorrhage of 2.5% (2/79 patients) compared to none in patients who received placebo.

Because intracerebral hemorrhages greater than 1 cm in diameter have been observed in patients taking LEQEMBI, additional caution should be exercised when considering the administration of anticoagulants or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI.

Other Risk Factors for Intracerebral Hemorrhage

Patients were excluded from enrollment in Study 2 for findings on neuroimaging that indicated an increased risk for intracerebral hemorrhage. These included findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage.

The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy, which has an increased risk for intracerebral hemorrhage.

Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for intracerebral hemorrhage and in particular for patients who need to be on anticoagulant therapy.

Monitoring and Dose Management Guidelines

Recommendations for dosing in patients with ARIA-E depend on clinical symptoms and radiographic severity *[see Dosage and Administration (2.3)]*. Recommendations for dosing in patients with ARIA-H depend on the type of ARIA-H and radiographic severity *[see Dosage and Administration (2.3)]*. Use clinical judgment in considering whether to continue dosing in patients with recurrent ARIA-E.

Baseline brain MRI and periodic monitoring with MRI are recommended *[see Dosage and Administration (2.3)]*. Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

There is no experience in patients who continued dosing through symptomatic ARIA-E, or through asymptomatic but radiographically severe ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E.

The Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) is a voluntary provider-enrolled patient registry that collects information on treatments for Alzheimer's disease, including LEQEMBI. Providers may obtain information about the registry at www.alz-net.org or contact alz-net@acr.org.

5.2 Hypersensitivity Reactions

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred in patients who were treated with LEQEMBI. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy. LEQEMBI is contraindicated in patients with a history of serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI.

5.3 Infusion-Related Reactions

In Study 2, infusion-related reactions were observed in 26% (237/898) of patients treated with LEQEMBI compared to 7% (66/897) of patients on placebo; and the majority (75%, 178/237) occurred with the first infusion. Infusion-related reactions were mostly mild (69%) or moderate (28%) in severity. Infusion-related reactions resulted in discontinuations in 1% (12/898) of patients treated with LEQEMBI. Symptoms of infusion-related reactions include fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.

After the first infusion in Study 1, 38% of patients treated with LEQEMBI had transient decreased lymphocyte counts to less than 0.9 $x10^9$/L compared to 2% in patients on placebo, and 22% of patients treated with LEQEMBI had transient increased neutrophil counts to greater than 7.9 $x10^9$/L compared to 1% of patients on placebo. Lymphocyte and neutrophil counts were not obtained after the first infusion in Study 2.

In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Prophylactic treatment with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids prior to future infusions may be considered.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Amyloid Related Imaging Abnormalities *[see Warnings and Precautions (5.1)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*
- Infusion-Related Reactions *[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 safety of LEQEMBI has been evaluated in 2090 patients who received at least one dose of LEQEMBI. In Studies 1 and 2 in patients with Alzheimer's disease, 1059 patients received LEQEMBI 10 mg/kg every two weeks. Of these 1059 patients, 50% were female, 79% were White, 15% were Asian, 12% were of Hispanic or Latino ethnicity, and 2% were Black. The mean age at study entry was 72 years (range from 50 to 90 years).

In the combined double-blind, placebo-controlled period and long-term extension period of Studies 1 and 2, 1604 patients received LEQEMBI for at least 6 months, 1261 patients for at least 12 months, and 965 patients for 18 months.

In the double-blind, placebo-controlled period in Study 2, patients stopped study treatment because of an adverse reaction in 7% of patients treated with LEQEMBI, compared to 3% of patients on placebo.

In Study 2, the most common adverse reaction leading to discontinuation of LEQEMBI was ARIA-H microhemorrhages that led to discontinuation in 2% (15/898) of patients treated with LEQEMBI compared to <1% (1/897) of patients on placebo. Adverse reactions reported in Study 2 are shown in Table 4.

Table 4: Adverse Reactions Reported in at Least 5% of Patients Treated With LEQEMBI 10 mg/kg Every Two Weeks and at Least 2% Higher than Placebo in Study 2

Adverse Reaction	LEQEMBI N=898 %	Placebo N=897 %
Infusion-related reactions	26	7
ARIA-H	14	8
ARIA-E	13	2
Headache	11	8
Superficial siderosis of central nervous system	6	3
Rash[1]	6	4
Nausea/Vomiting	6	4

[1]Rash includes acne, erythema, infusion site rash, injection site rash, rash, rash erythematous, rash pruritic, skin reactions, and urticaria.

Less Common Adverse Reactions

Atrial fibrillation occurred in 3% of patients treated with LEQEMBI compared to 2% in patients on placebo. In Study 1, lymphopenia or decreased lymphocyte count were reported in 4% of patients treated with LEQEMBI after the first dose, compared to less than 1% of patients on placebo *[see Warnings and Precautions (5.3)]*; lymphocytes were not measured after the first dose in Study 2.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on LEQEMBI use in pregnant women to evaluate for a drug associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. No animal studies have been conducted to assess the potential reproductive or developmental toxicity of LEQEMBI.

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. The background risk of major birth defects and miscarriage for the indicated population is unknown.

8.2 Lactation

Risk Summary

There are no data on the presence of lecanemab-irmb in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Published data from other monoclonal antibodies generally indicate low passage of monoclonal antibodies into human milk and limited systemic exposure in the breastfed infant. The effects of this limited exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LEQEMBI and any potential adverse effects on the breastfed infant from LEQEMBI or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of LEQEMBI in pediatric patients have not been established.

8.5 Geriatric Use

In Studies 1 and 2, the age of patients exposed to LEQEMBI 10 mg/kg every two weeks (n=1059) ranged from 50 to 90 years, with a mean age of 72 years; 81% were 65 years and older, and 39% were 75 years and older. No overall differences in safety or effectiveness of LEQEMBI have been observed between patients 65 years of age and older and younger adult patients.

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Amyloid Related Imaging Abnormalities

Inform patients that LEQEMBI may cause Amyloid Related Imaging Abnormalities or "ARIA". ARIA most commonly presents as a temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain. Inform patients that most people with swelling in areas of the brain do not experience symptoms, however, some people may experience symptoms such as headache, confusion, dizziness, vision changes, nausea, aphasia, weakness, or seizure. Instruct patients to notify their healthcare provider if these symptoms occur. Inform patients that events of intracerebral hemorrhage greater than 1 cm in diameter have been reported infrequently in patients taking LEQEMBI, and that the use of anticoagulant or thrombolytic medications while taking LEQEMBI may increase the risk of bleeding in the brain. Notify patients that their healthcare provider will perform MRI scans to monitor for ARIA *[see Warnings and Precautions (5.1)]*.

Inform patients that although ARIA can occur in any patient treated with LEQEMBI, there is an increased risk in patients who are ApoE ε4 homozygotes and that testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Inform patients that if testing is not performed, it cannot be determined if they are ApoE ε4 homozygotes and at a higher risk for ARIA.

Patient Registry

Advise patients that the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) is a voluntary provider-enrolled patient registry that collects information on treatments for Alzheimer's disease, including LEQEMBI. Encourage patients to participate in the ALZ-NET registry *[see Warnings and Precautions (5.1)]*.

Hypersensitivity Reactions

Inform patients that hypersensitivity reactions, including angioedema and anaphylaxis have occurred in patients who were treated with LEQEMBI. Advise patients to seek immediate medical attention if they experience any symptoms of serious or severe hypersensitivity reactions *[see Warnings and Precautions (5.2)]*.

Infusion-Related Reactions

Advise patients of the potential risk of infusion-related reactions, which can include flu-like symptoms, nausea, vomiting, and changes in blood pressure, the majority of which occur with the first infusion *[see Warnings and Precautions (5.3)]*.

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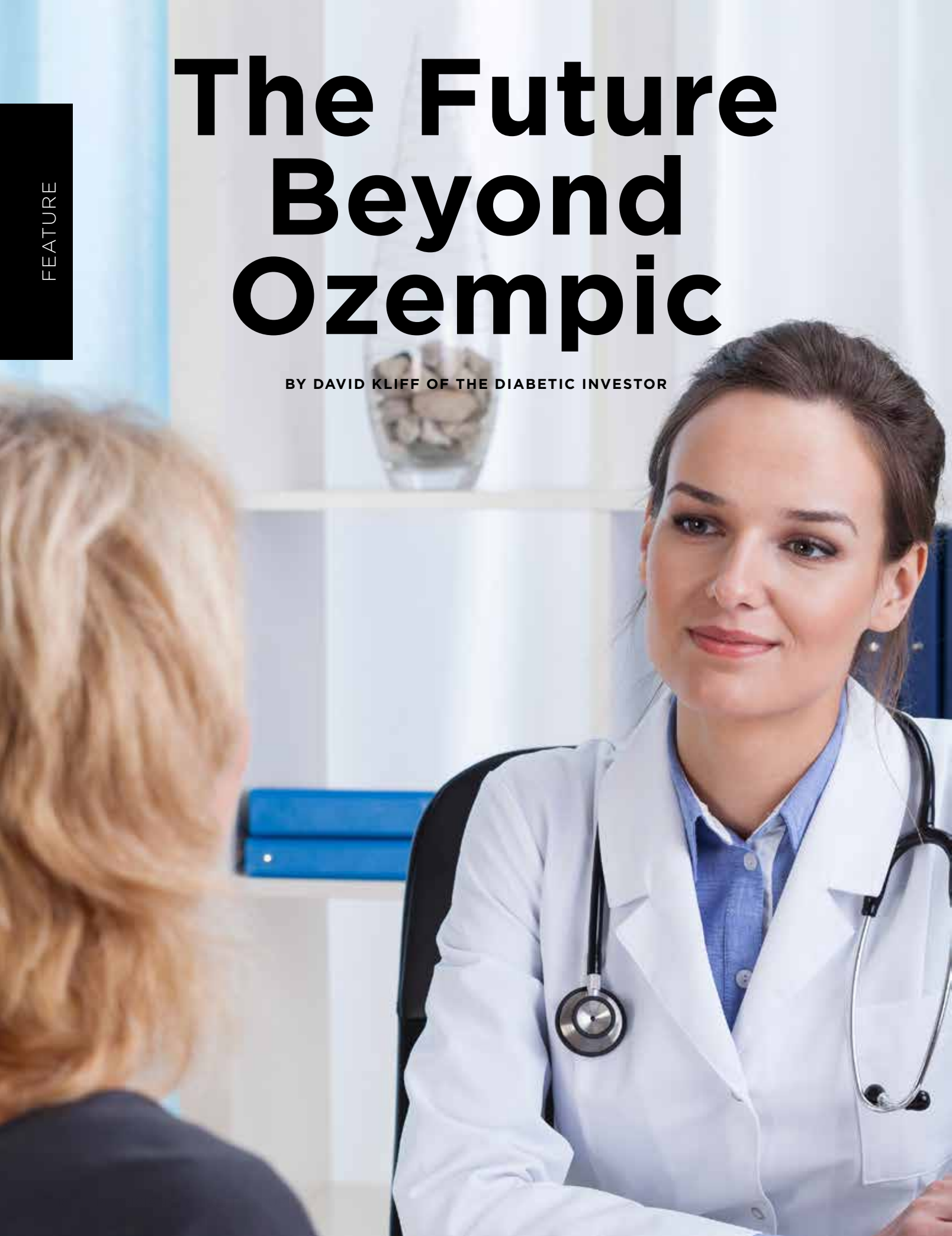


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FEATURE

The Future Beyond Ozempic

BY DAVID KLIFF OF THE DIABETIC INVESTOR



It almost seems presumptuous to look beyond the current crop of drugs like Ozempic, Wegovy and Mounjaro. All three have patent protection well into the next decade, sales continue to skyrocket plus Novo Nordisk and Eli Lilly have robust pipelines of follow on products. This is a huge and growing market that is vastly underpenetrated. Still, it would be foolish not to look ahead, as Novo and Lilly aren't the only companies who want to play in this sandbox.

Before we look ahead, let's review the current situation. Novo has Ozempic and Wegovy, in addition to Rybelsus which is currently the only oral in the space. Lilly has Mounjaro. It should be noted that Bydureon also falls in this class of drugs but has failed to capitalize on the insatiable demand for these drugs. Byetta the very first in this category but being a twice daily injection is out of touch with the others which are once weekly administration.

Before we examine what's coming, it's critical to examine the changing attitude towards obesity/diabetes management. Thankfully people are finally recognizing that obesity and to some extent Type 2 diabetes are not character flaws. These are chronic conditions that require management. The success of these drugs has opened new doors of thought, obesity is no longer being seen as a character flaw and that it's a real condition just as diabetes is. As we all know there are several costly comorbidities associated with obesity and poorly controlled diabetes. It's appropriate to state that these two chronic conditions are not just creating a healthcare but economic crisis.

Along with these changing attitudes and treatment paradigms comes several new therapy options. Both Novo and Lilly are working on oral versions of their injectable options. Rybelsus the only current oral in the category. The drug works well IF the administration protocol is followed. Patients must take it on an empty stomach with no more than 4 ounces of water and not eat for a minimum of 30 minutes after. This is why most when prescribing the drug tell their patients to take the drug in the morning when they wake up.

The newer oral options don't come with these dosing restrictions. They can be taken basically anytime with any amount of liquid. And just as the injectable options are very effective, the data we have seen so far on their oral versions looks equally effective. There is no doubt in my mind that while being an injectable hasn't hurt sales, oral versions will be even more successful. Given the choice most will choose pills over injections.

With orals well on their way, these drugs will evolve from one size fits all to more targeted approaches. The fact is not every patient is morbidly obese and needs to lose substantial amounts of weight. In the future different drugs will produce different weight loss targets. Some patients will require the maximum, others less so. Additionally, these offerings will be used in combination, starting with one to lose the weight and then transitioning to another to keep the weight off.

There is some debate as to the relevance of less frequent dosing. Byetta the first drug in the category was injected twice daily. Along comes Victoza which dosed once per day, and now there are multiple once weekly options. Some believe that once monthly would lead to poorer patient adherence. As one physician put it, most everyone does something once a week, laundry grocery shopping etc. But there aren't too many things you do once a month. Or to put simply it's easier to form a weekly habit than it is to form a monthly one.

The other area of interest is alternate delivery systems. Rather than injecting or taking pills the drug would be automatically dosed via an implantable device. This isn't as far-fetched as you'd think, as unlike insulin there is little chance of adverse hypoglycemic events, which as we know can be serious even life-threatening. The benefit with an implantable device is adherence is 100%. Now some will say, what happens if the device fails or how is it implanted? Great questions of course and we all know that no device works 100% of the time. However, the implantation procedure is actually very simple and can be done in the office. Even better there are reimbursement codes for this procedure. In the past the device was implanted, removed after six months and new one inserted. Whether this becomes a reality is of course based on multiple factors but it's an intriguing approach.

Keep in mind that this market is still in its very early stages. That the current offerings are very effective and will continue to see increased adoption. Reimbursement is improving and should Medicare begin to cover these drugs the floodgates could swing wide open. Still, it's interesting to look ahead. It's also very positive that attitudes along with drugs are improving. Lots of positives in this very large very underpenetrated developing market.

About the Author

David Kliff is the founder and publisher of Diabetic Investor, the premier publication that provides in-depth analysis of the business of diabetes. With over 30 years of experience as a diabetes industry analyst, consultant, and speaker, David has a unique perspective and insight into the diabetes market and its trends, challenges, and opportunities.

David leverages his financial expertise and personal experience as a person living with diabetes to deliver unbiased and candid commentary on the diabetes biotech, and device sector. He closely monitors the existing and emerging products, services, and technologies that promise to improve the lives of people with diabetes. He also connects the dots between the patients, the companies, the research community, and the emerging technology, and offers compelling and provocative insights on the industry.



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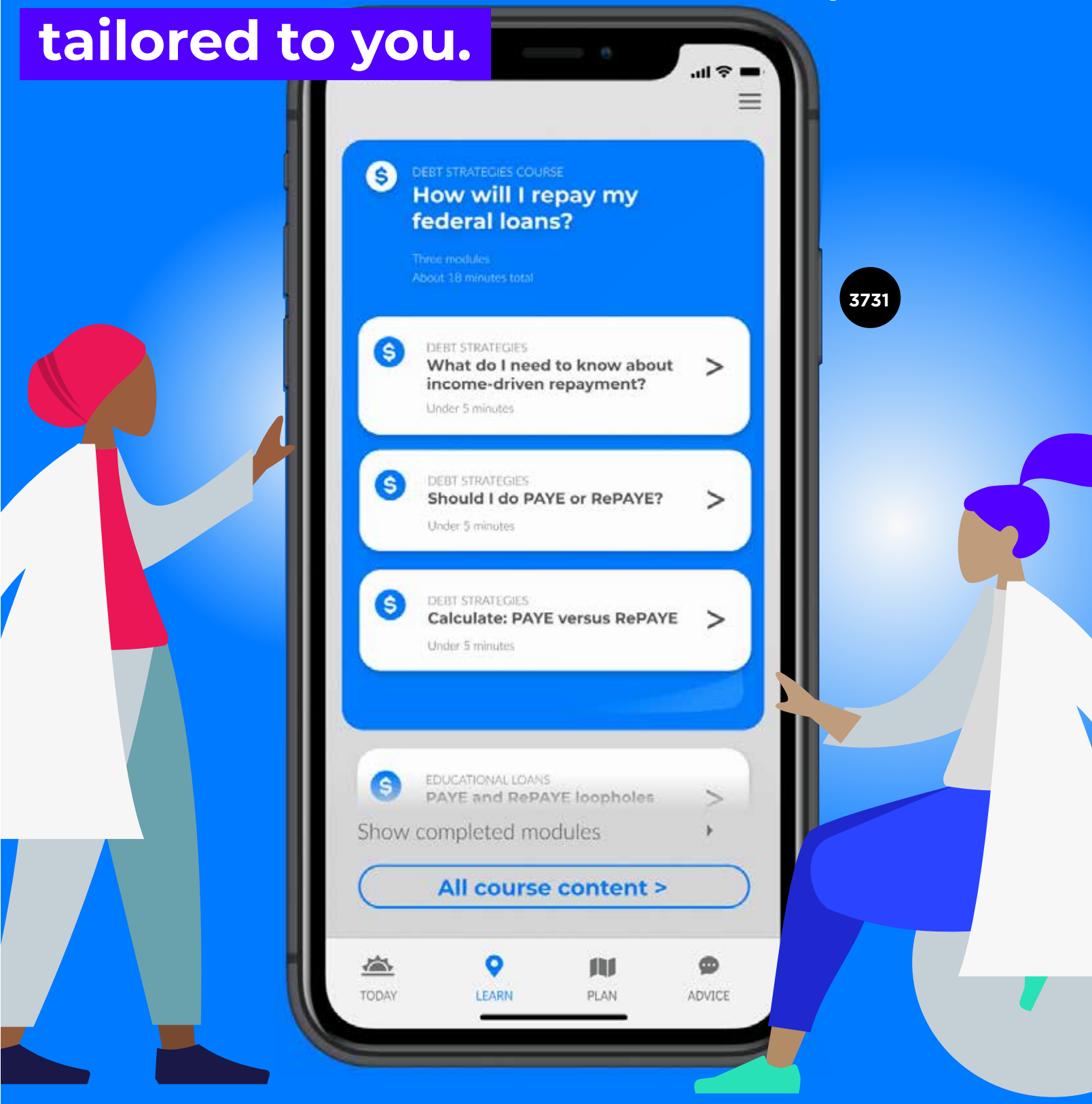
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QUANTAFLO® PAD

From Semler Scientific

QuantaFlo® PAD is an easy to use, accurate, point of care, non-invasive solution that aids in the early detection of peripheral arterial disease (PAD). This FDA cleared device can be administered by a medical aide in less than 5 minutes. As published in the Journal of Vascular Surgery and the American Journal of Preventive Medicine, QuantaFlo detected undiagnosed PAD in 31.6% of patients +65.1 QuantaFlo is portable and integrates with other technologies and platforms. It is ideal for both home and clinic environments.

1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

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NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

From Nova Biomedical

The U.S. FDA has cleared Nova Primary as a blood glucose reference analyzer that fills the need for a new reference analyzer to replace the YSI STAT PLUS 2300 (YSI, Inc., Yellow Springs, OH). Manufacturers of blood glucose measuring devices and clinical diabetes researchers have relied on the YSI 2300 as a reference and correlation analyzer. However, YSI, Inc. no longer supports the analyzer, and its discontinuation has left a critical industry void. With today's FDA clearance, Nova Primary from Nova Biomedical is now available in the U.S. and worldwide.

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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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- 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)

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- 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



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BIOFIRE SPOTFIRE

From bioMerieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

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ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

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- 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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From Abbott

With reduced budgets, shrinking laboratory space and staffing challenges, many laboratories need a solution that lets them work smarter with less. The CELL-DYN Emerald 22 AL is a full performance, automated optical 5-part differential analyzer that delivers smarter results for small to midsize clinical laboratories.

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From HORIBA Medical

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PERIPHERAL ARTERIAL DISEASE



PAD TESTING SYSTEMS IDEAL FOR PRIMARY CARE TO VASCULAR SPECIALISTS

from Newman Medical

Your Patients Trust YOU To Find Their Peripheral Artery Disease
- High-risk patients include those over 65, diabetics, and smokers.
- If left untreated, 25% of patients with PAD will experience a heart attack or stroke within 5 years.
- PAD symptoms are often mistaken for arthritis or old age.

The simpleABI Cuff-Link System is Easy to Learn and Use.
- With a push-button remote, automatic calculations, and waveforms, it's incredibly user-friendly.
- Reports are straightforward to save and share since the system is PC-based.

Outstanding Value and Reimbursements
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- Medicare reimbursements vary by exam and location, averaging from $91 to $174.

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QUANTAFLO® PAD

From Semler Scientific

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The BIOFIRE® FILMARRAY® TORCH is a fully integrated, random, and continuous-access system designed to meet your laboratory's syndromic infectious disease testing needs. The benchtop footprint of the BIOFIRE TORCH saves precious lab space, and its scalability meets high throughput demands. BIOFIRE® FILMARRAY® Link Software automatically uploads patient results. Fully compatible with all BIOFIRE® FILMARRAY® Panels intended for use in CLIA-moderate settings, the BIOFIRE TORCH helps you maximize efficiency and productivity.

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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

From Sekisui Diagnostics

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

From Sekisui Diagnostics

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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Harbour Village Beach Club

Bonaire's Exclusive Escape into Underwater Wonders and Above-ground Tranquility

BY JEN HELMLE

Tucked away on the leeward side of Bonaire, 30 miles east of Curaçao and 86 miles east of Aruba, and outside the hurricane zone the Harbour Village Beach Club stands as a testament to Caribbean luxury. It is truly a tropical paradise where azure waves kiss ivory sands and the days drift by under the benevolent gaze of the tropical sun. For those in search of a distinguished travel experience that combines the allure of seclusion with the adventure of the marine world, this resort is an undisputed gem!

First Impressions

Arriving at Harbour Village Beach Club is like stepping into a postcard. Just a quick 15-minute shuttle from Flamingo International Airport, the beautiful open-air lobby adorned with lush tropical plants and the soothing sounds of their adjacent marina immediately sets the stage for what's to come: an intimate encounter with Caribbean charm. The resort, named "Bonaire's Leading Hotel", World Travel Awards, for 16 years and Bonaire's Best Boutique Hotel by Caribbean Journal, promises an experience that's as exclusive as it is exquisite.

Accommodations: Personalized Retreats

Staying true to its vision of personalized service, the resort offers a variety of accommodations to suit every taste and need. From Beachfront Suites that offer unimpeded views of the turquoise waters to Marina Front Rooms that provide a serene view of yachts and dive boats bobbing gently in the marina, each lodging option is a sanctuary of comfort.

The décor of the rooms and suites is an elegant mix of traditional Caribbean aesthetics and modern comfort, with rooms featuring plush bedding, rich wood furnishings, and all the amenities expected of a luxury retreat. Each room is a private escape, with balconies or patios that invite guests to breathe in the salt-tinged air and let the rhythm of the waves be the soundtrack of your stay.

Culinary Delights: Flavorful Journeys

The gastronomic experience at Harbour Village is an adventure in its own right. La Balandra, the resort's beachfront restaurant, is designed to resemble an antique Spanish ship, offering a dining ambiance that is unique and enchanting. The menu, curated by skilled local chefs, is a celebration of Caribbean flavors with international influences, showcasing the freshest local seafood and produce. Each afternoon we would be presented with local catch options from freshly caught Barracuda to Caribbean Lobster all magnificently prepared for dinner later that evening. For a truly personalized experience, private beach dining under the stars can be arranged, where the melody of the ocean is your serenade.

Diving and Snorkeling: Underwater Exploration

Bonaire is often hailed as a diver's paradise, and the Harbour Village Beach Club is at the heart of this underwater marvel. The resort boasts a PADI five-star dive center, Great Adventures Bonaire, offering personalized dive experiences for both beginners and seasoned divers. The house reef, just a short swim from the beach, is a thriving ecosystem home to seahorses, parrotfish, huge Tarpon and even the occasional turtle. The coral restoration project, an initiative Harbour Village is deeply passionate about, is something guests can participate in, marrying the concept of vacation with conservation. Divers can adopt a coral and leave a lasting legacy in Bonaire's waters. There is also a live underwater video stream allowing those not









fortunate enough to be there in person to still participate in the splendor of this amazing aquatic environment.

Activities: Beyond the Beach

While the allure of the beach is undeniable, Harbour Village encourages guests to explore beyond. On-site amenities such as a fitness center, tennis courts, and a spa offer a counterbalance to the laid-back beach life. For those looking to immerse themselves in local culture, the resort can arrange visits to Bonaire's flamingo sanctuaries or the historic capital of Kralendijk. Sailing and fishing excursions are also at your fingertips. Whether you're looking to hook a big catch or simply sail into the sunset, the resort's concierge can customize the experience for you.

Sustainability: Harmony with Nature

In a time where eco-consciousness is more important than ever, Harbour Village is proud of its commitment to sustainability. The resort has implemented several eco-friendly practices, from solar panels to a ban on single-use plastics, ensuring that your stay is as kind to the environment as it is enjoyable for you.

Relaxation: The Spa at Harbour Village

No personalized travel experience would be complete without a touch of indulgence. The Spa at Harbour Village is a haven of tranquility, offering a menu of treatments inspired by the island's natural beauty. From rejuvenating facials using local aloe to massages that draw on the healing properties of the Caribbean sea, every treatment is designed to harmonize body and mind.

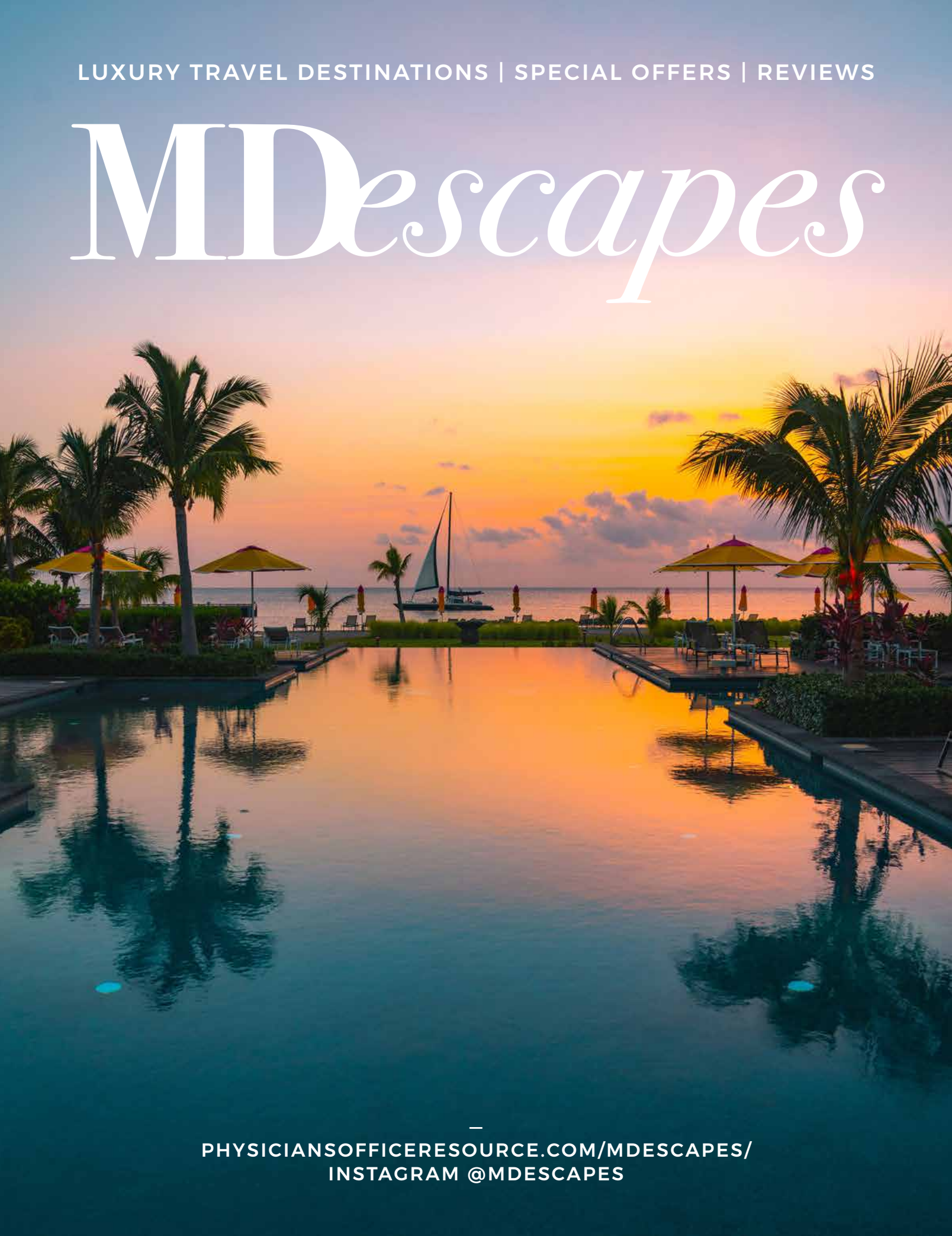
Exclusive Offers: Tailored Experiences

Harbour Village is not just about off-the-shelf vacation packages. The resort takes pride in crafting offers that cater to the desires of its guests. From diving packages to wellness retreats, the options are customizable, ensuring that your stay is exactly how you envision it.

Harbour Village Beach Resort is more than a luxurious getaway; it's a unique experience that combines the beauty of Bonaire with unmatched hospitality. Whether it's a family vacation, a romantic getaway, or a solo adventure, the resort caters to all with its blend of relaxation, adventure, and culinary delights. For those seeking a serene and exclusive Caribbean adventure, I cannot recommend Harbour Village Beach Resort strongly enough…it is amazing in every way imaginable!

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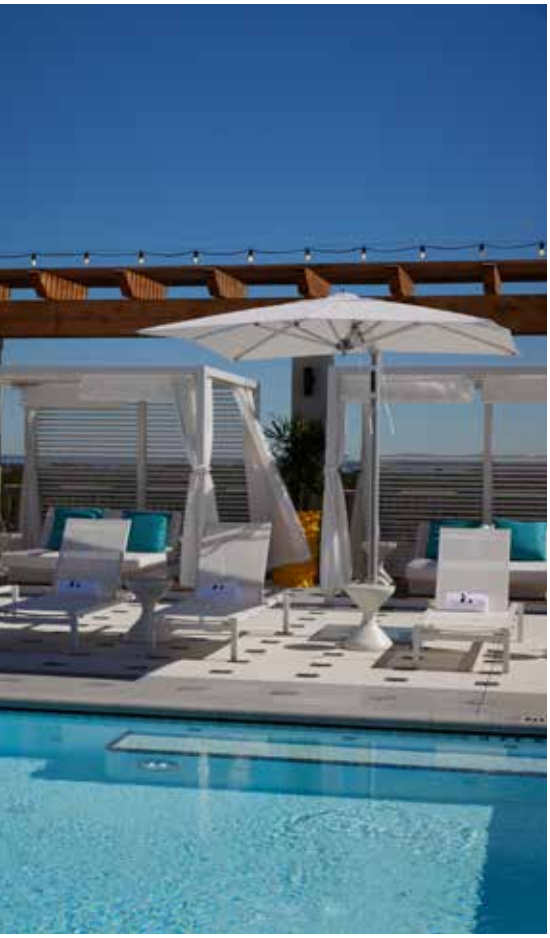
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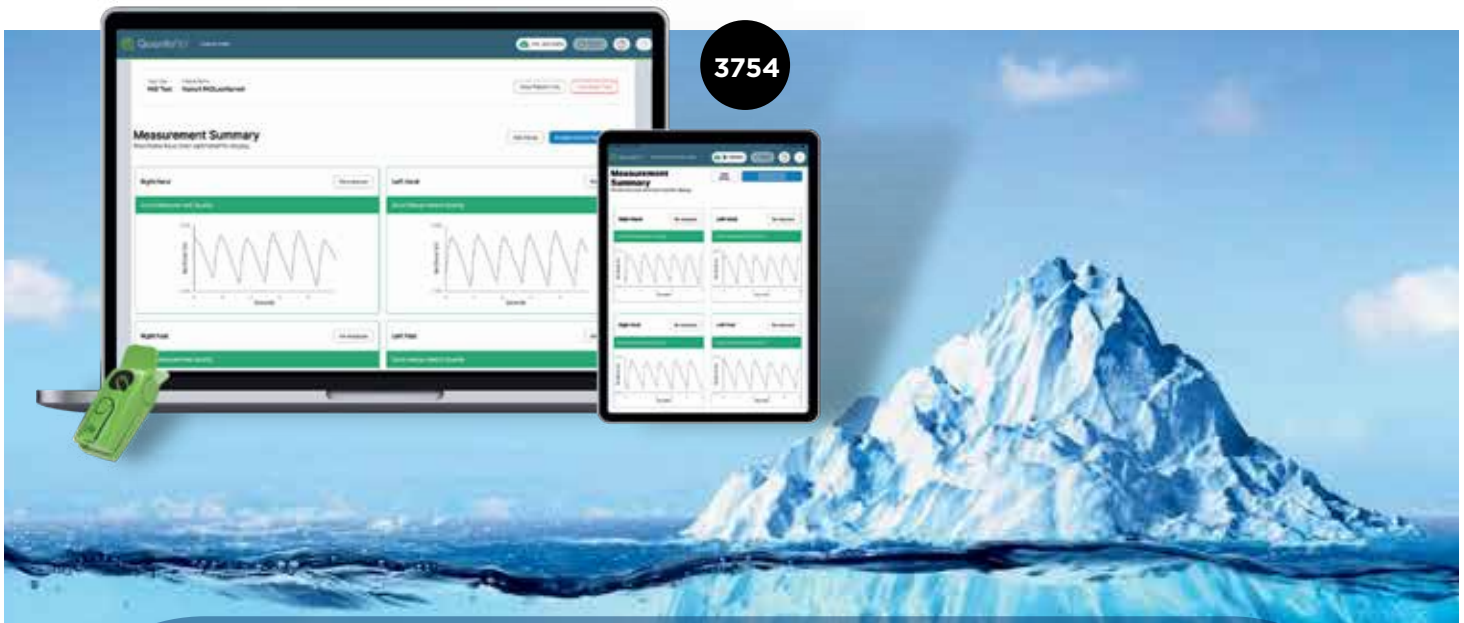
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2. Diehm, C., Allenberg, J. R., Pittrow, D., Mahn, M., Tepohl, G., Haberl, R. L., Darius, H., Burghaus, I., Trampisch, H. J., & German Epidemiological Trial on Ankle Brachial Index Study Group (2009). Mortality and vascular morbidity in older adults with asymptomatic versus symptomatic peripheral artery disease. Circulation, 120(21), 2053–2061. https://doi.org/10.1161/CIRCULATIONAHA.109.865600

ML00190 Rev A