2024 | Issue 1

Physicians office Resource

Resources for You, Your Patients, & Your Practice



HELPING PATIENTS BETTER UNDERSTAND TESTOSTERONE THERAPY

MDescapes: Top Travel Trends and Destinations for 2024

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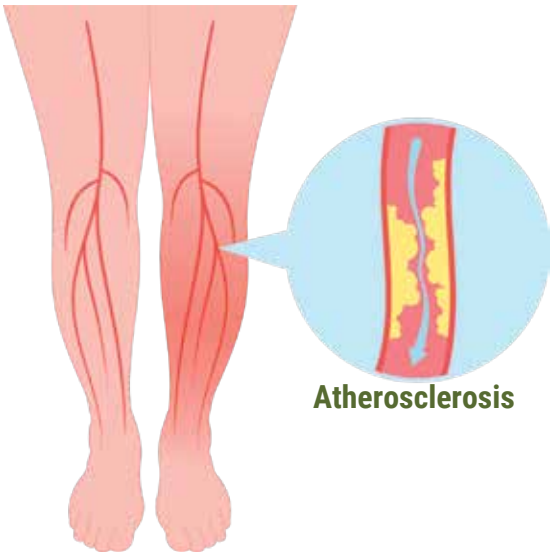
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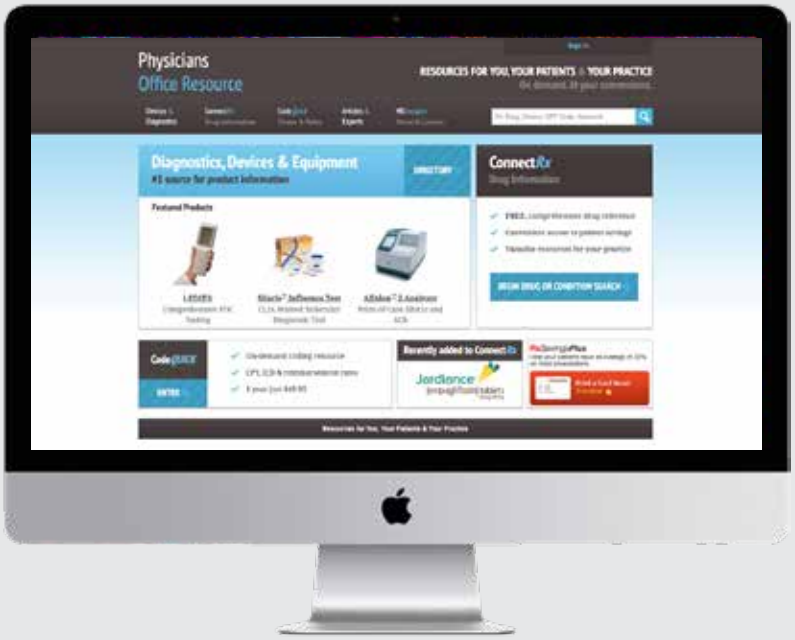
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PUBLISHER
Aaron R. Medaris
amedaris@physiciansofficeresource.com

CEO
Andrew C. Nimmo
acnimmo@physiciansofficeresource.com

PRESIDENT
John D. Pasquale
jpasquale@pharmaconnect.com

BUSINESS MANAGER
Marci J. Hills
mhills@physiciansofficeresource.com

TRAVEL EDITOR
Brandi L. Brower

EDITORIAL BOARD
Michael Paquin, FHIMSS
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STAFF WRITER
Dylan J. Chadwick

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TABLE OF CONTENTS



HELPING PATIENTS BETTER UNDERSTAND TESTOSTERONE THERAPY

PAGE 6

Celebrities such as Joe Rogan, Jeff Bezos, Alan Ritchson, and Sylvester Stallone all tout the benefits of utilizing testosterone therapy or TT for short. Heck you've probably seen your friends on Instagram and heard from your neighbor down the street how they've gotten leaner, shed fat faster, gained more energy, and reclaimed their sex life all because of TT. Sounds like quite the miracle treatment for aging males. With a lot of this "medical" information coming from non- medical sources, how to you best help your patients understand the true benefits and risks associated with TT?

18

ATRIAL FIBRILLATION:
The Case for Cardiac Catheter Ablation First over Drug Treatment

32

MDescapes:
Top Travel Trends and Destinations for 2024

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FEATURE

HELPING PATIENTS BETTER UNDERSTAND TESTOSTERONE THERAPY

BY PHYSICIANS OFFICE RESOURCE



If you're a sports fan like me, you've probably seen the commercials that run on ESPN promoting products to help men with low testosterone, or what they refer to as "Low-T." Celebrities such as Joe Rogan, Jeff Bezos, Alan Ritchson, and Sylvester Stallone all tout the benefits of utilizing testosterone therapy or TT for short. Heck you've probably seen your friends on Instagram and heard from your neighbor down the street how they've gotten leaner, shed fat faster, gained more energy, and reclaimed their sex life all because of TT. Sounds like quite the miracle treatment for aging males. With a lot of this "medical" information coming from non-medical sources, how to you best help your patients understand the true benefits and risks associated with TT?

Chances are, as a primary care physician you've received plenty of questions about TT; given that the majority of testosterone prescriptions are written by primary care doctors. To help you be better prepared for those questions, we'll look at important aspects that patients and HCPs should understand when contemplating if this therapy, such as, what is testosterone, how should we best test for it, what are the benefits, risks, and important facts patients should know about TT before beginning treatment.

With a lot of this "medical" information coming from non-medical sources, how to you best help your patients understand the true benefits and risks associated with TT?

Testosterone

Testosterone is a sex hormone that plays a crucial role in the development and maintenance of male reproductive tissues and characteristics. It is produced primarily in the testicles in males and in smaller amounts in the ovaries in females. Testosterone is responsible for the growth of male reproductive organs during puberty, the development of facial and body hair, deepening of the voice, and the increase in muscle mass. It also contributes to bone density, fat distribution, and overall well-being. While it is often associated with males, females also produce small amounts of testosterone, contributing to their hormonal balance and reproductive health. Here are some additional functions of testosterone in males:

1. Testosterone is also crucial for libido and sexual function. Testosterone is associated with the male sex drive (libido) and is crucial for normal sexual function. It influences sexual arousal and the ability to achieve and maintain erections.

2. Having healthy levels of testosterone can affect mood and energy levels. Low testosterone levels may contribute to fatigue, mood swings, and a decrease in overall energy.

3. Testosterone influences fat distribution in the body. Lower levels of testosterone may lead to an increase in body fat, especially around the abdomen.

4. While the relationship is complex, some studies suggest that testosterone may play a role in cognitive functions, including memory and spatial abilities.

Testosterone Changes with Age

Testosterone levels typically undergo changes with age, and these changes are a natural part of the aging process. The pattern of testosterone level changes can vary among individuals, but there are general trends. Here's an overview of how testosterone levels change with age in males:

Puberty (Adolescence): Testosterone levels begin to rise during puberty, typically starting around the age of 13 to 15. This surge in testosterone is responsible for the development of secondary sexual characteristics, such as facial and body hair growth, deepening of the voice, and increased muscle mass.

Young Adulthood: Testosterone levels peak in early adulthood, usually in the late teens to early twenties. During this period, males experience optimal levels of testosterone, contributing to reproductive health, muscle development, and overall well-being.

Adulthood (30s and 40s): As males reach their late twenties and beyond, testosterone levels may gradually decline. This decline is a natural part of aging but is typically gradual and varies among individuals. Some men may experience a more noticeable decline in testosterone than others.

Midlife (50s and 60s): Testosterone levels may continue to decline further in midlife. This phase is sometimes referred to as andropause, similar to the female menopause. However, the decline in testosterone is generally more gradual and less pronounced than the hormonal changes seen in menopause.

Older Age (70s and beyond): Testosterone levels may continue to decrease with advancing age. However, the rate of decline varies, and not all older men experience significant decreases in testosterone. Some individuals maintain relatively stable testosterone levels throughout their lives.

It's important to note that while testosterone levels tend to decline with age, not all age-related symptoms are solely attributed to lower testosterone. Other factors, such as lifestyle, diet, exercise, and overall health, can also influence well-being in aging individuals.

Testing Hormone Levels – Free Vs. Bound

Testosterone in the blood circulates in two main forms:

1. Bound Testosterone: Testosterone can bind to proteins, primarily to a protein called sex hormone-binding globulin (SHBG) and, to a lesser extent, to albumin. Testosterone that is bound to these proteins is considered inactive because it is not readily available for use by cells.

2. Free Testosterone: Some testosterone circulates in the blood in an unbound or free form. This is the portion of testosterone that is not bound to proteins and is considered bioavailable. Free testosterone is available for use by cells and tissues in the body.

In addition to bound and free testosterone, there is also a third category known as bioavailable testosterone. Bioavailable testosterone includes both free testosterone and testosterone that is loosely bound to albumin, and it represents the fraction of testosterone that is readily accessible for cellular use.

There are three types of blood tests measure these different forms of testosterone:

1. A total testosterone test measures free testosterone and bound testosterone that's attached to proteins. This is the most common type of test.

2. A free testosterone test measures only the "active" form of testosterone. This test is less common, but it may be useful for diagnosing certain medical conditions.

3. A bioavailable testosterone test measures free testosterone and testosterone that's loosely attached to a blood protein called albumin. This test isn't commonly done. But like a free testosterone test, it may help diagnose certain medical conditions.

Total testosterone levels can vary among individuals, and what is considered a "normal" range can depend on the laboratory methods used for testing. Additionally, the reference ranges may differ slightly between different sources.

Typically, total testosterone levels are measured in nanograms per deciliter (ng/dL). Here are general guidelines for normal total testosterone levels in males based on age (the values provided here are general guidelines and may not be applicable to every individual):

Adolescence:
Normal Range: 300-1,200 ng/dL

Adults (20s to 40s):
Normal Range: 300-1,000 ng/dL

Adults (50s and older):
Normal Range: 240-950 ng/dL

Free testosterone levels, like total testosterone levels, can vary among individuals, and normal ranges may be influenced by factors such as the laboratory method used for testing. Additionally, free testosterone levels are usually reported as a percentage of total testosterone.

Typically, free testosterone levels are expressed as a percentage of total testosterone. Here are general guidelines for normal free testosterone levels in males based on age (the values provided here are general guidelines and may not be applicable to every individual):

Adolescence:
Normal Range: 1.6% to 2.9% of total testosterone

Adults (20s to 40s):
Normal Range: 1.5% to 2.5% of total testosterone

Adults (50s and older):
Normal Range: 1.0% to 2.2% of total testosterone

Testosterone Therapies

Testosterone therapy, also known as androgen replacement therapy, is a medical intervention aimed at supplementing or replacing testosterone in individuals with low testosterone levels. Here are some common testosterone replacement therapies:

Testosterone Injections: Intramuscular injections are a common method of administering testosterone. Injections are usually given into the muscles, such as the gluteal muscles, and are typically administered every 1-2 weeks.

Testosterone Gel or Patch: Topical formulations, such as gels or patches, are applied to the skin, allowing for absorption of testosterone into the bloodstream. Gels are typically applied to the shoulders, upper arms, or abdomen, while patches are applied to various areas of the body.

Testosterone Pellets: Testosterone pellets are small, subcutaneous implants that are inserted under the skin, usually in the hip or buttock area. These pellets release a slow, steady amount of testosterone over several months.

Testosterone Buccal System: This involves a small, medicated patch that is applied to the upper gum, releasing testosterone through the oral mucosa.

Oral Testosterone: While less commonly prescribed, oral testosterone medications are available. However, they are associated with potential liver toxicity and are not as widely used as other forms of testosterone replacement.

Testosterone Therapy Benefits

The potential benefits of testosterone therapy can vary among individuals and depend on factors such as the severity of the hormonal deficiency, overall health, and individual response to treatment. Here are some potential benefits associated with testosterone therapy:



Improved Libido and Sexual Function: Testosterone plays a key role in sexual health, and individuals with low testosterone levels may experience improvements in libido and sexual function with testosterone therapy.

Increased Muscle Mass and Strength: Testosterone is involved in the development and maintenance of muscle mass. Testosterone therapy may help individuals with low testosterone levels increase muscle mass and strength.

Enhanced Mood and Energy Levels: Some individuals with low testosterone may experience fatigue, mood swings, or low energy levels. Testosterone therapy may contribute to improved mood and energy.

Bone Density Maintenance: Testosterone is important for bone health, and its deficiency may contribute to decreased bone density. Testosterone therapy may help maintain or improve bone density in individuals with low testosterone.

Improved Cognitive Function: While the relationship is complex, some studies suggest that testosterone may play a role in cognitive functions, including memory and spatial abilities. Testosterone therapy may have cognitive benefits in some individuals.

Reduction in Fat Mass: Testosterone is associated with fat metabolism, and individuals with low testosterone may have an increased risk of accumulating body fat, especially around the abdomen. Testosterone therapy may contribute to a reduction in fat mass.

Testosterone Therapy Risks

It's important to emphasize that testosterone therapy is not suitable for everyone, and its use should be carefully considered and monitored. Before starting any form of testosterone therapy, individuals should undergo a comprehensive evaluation, including a physical examination and blood tests to measure testosterone levels.

Potential risks and side effects of testosterone therapy include:

- Polycythemia: An increase in red blood cell count.
- Acne or oily skin: Some individuals may experience skin-related side effects.
- Breast enlargement: Known as gynecomastia, this can occur in some cases.
- Sleep apnea: Testosterone therapy may worsen sleep apnea in susceptible individuals.
- Long-term safety and potential cardiovascular risk associated with testosterone therapy are still a subject of ongoing research, and healthcare providers carefully weigh the benefits and risks before recommending such treatment. It's crucial for individuals considering testosterone therapy to have open and informed discussions with their healthcare provider to make decisions based on their specific health needs and circumstances.

Is Testosterone Therapy Right for your patient?

If a patient comes to you for the sole purpose of shredding fat and putting on muscle because of his buddy on Instagram has been posting daily about how his life has changed for the better because of TT. Be sure to have a real conversation about what testosterone therapy is truly for. It's not for everyone and there are some real risks associated with it. But if a patient comes in expressing concern for fatigue, low libido, increased body fat, changes in hair growth, etc. it may be wise to discuss being tested for Low-T and potential therapy options.

THERE'S A NEW NAME IN THE TREATMENT OF OBESITY

Introducing Zepbound (tirzepatide)—the first and only GIP and GLP-1 receptor agonist for the treatment of obesity[1]



GIP=glucose-dependent insulinotropic polypeptide; GLP-1=glucagon-like peptide-1.

Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound.

Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Acute Gallbladder Disease: Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Acute Pancreatitis: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, or tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at

Please see Important Safety Information and Boxed Warning about possible thyroid tumors, including thyroid cancer, here and Brief Summary on the following pages.



Important Safety Information (continued)

higher risk for development of pancreatitis on Zepbound. Observe patients for signs and symptoms, including persistent severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting. If pancreatitis is suspected, discontinue Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound-treated patients had severe hypersensitivity reactions compared to no placebo-treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown if such patients will be predisposed to these reactions with Zepbound.

Hypoglycemia: Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2, hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). Hypoglycemia has also been associated with Zepbound and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Suicidal Behavior and Ideation: Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

The most common adverse reactions, reported in ≥5% of patients treated with Zepbound are: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, and gastroesophageal reflux disease.

Drug Interactions: Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

Pregnancy: Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Zepbound when a pregnancy is recognized. Available data with tirzepatide in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Zepbound (tirzepatide) during pregnancy. Pregnant patients exposed to Zepbound and healthcare providers are encouraged to contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Lactation: There are no data on the presence of tirzepatide or its metabolites in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zepbound and any potential adverse effects on the breastfed infant from Zepbound or from the underlying maternal condition.

Females and Males of Reproductive Potential: Use of Zepbound may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation.

Pediatric Use: The safety and effectiveness of Zepbound have not been established in pediatric patients less than 18 years of age.

Please see Brief Summary on the following pages, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

ZP HCP ISI 08NOV2023

Reference: 1. Zepbound. Prescribing Information. Lilly USA, LLC.

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PP-ZP-US-0036 11/2023
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Lilly

Zepbound™ (tirzepatide) Brief Summary: Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

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WARNINGS AND PRECAUTIONS:

Risk of Thyroid C-Cell Tumors: In rats, tirzepatide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) in a 2-year study at clinically relevant plasma exposures [see Nonclinical Toxicology]. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined. Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound; including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Acute Gallbladder Disease: Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Acute Pancreatitis: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists or tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Zepbound. After initiation of Zepbound, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound-treated patients had severe hypersensitivity reactions compared to no placebo-treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with GLP-1 receptor agonists. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with Zepbound.

Hypoglycemia: Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2 , hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). There is also an increased risk of hypoglycemia in patients taking tirzepatide in combination with insulin.

Hypoglycemia has also been associated with Zepbound and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Suicidal Behavior and Ideation: Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

ADVERSE REACTIONS

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. Zepbound was evaluated for safety in 2 randomized, double-blind, placebo-controlled trials that included 2519 adult patients with overweight or obesity treated with Zepbound for up to 72 weeks and a 4-week off drug follow-up period [see Clinical Studies]. The mean age of patients was 47 years and 37% were male. The population was 72% White, 12% Asian, 8% Black or African American, and 7% American Indian or Alaska Native; 51% identified as Hispanic or Latino ethnicity. Baseline characteristics included an average BMI of 37.4 kg/m^2 , 29% with a BMI ≥40 kg/m^2 , 41% with hypertension, 37% with dyslipidemia, 25% with type 2 diabetes mellitus, 7% with obstructive sleep apnea, and 4% with cardiovascular disease. Across both trials, 4.8%, 6.3%, and 6.7% of patients treated with 5 mg, 10 mg, and 15 mg of Zepbound, respectively, permanently discontinued treatment as a result of adverse reactions compared to 3.4% of patients treated with placebo. The majority of patients who discontinued Zepbound due to adverse reactions did so during the first few months of treatment due to gastrointestinal adverse reactions.

Common Adverse Reactions: In the pool of placebo-controlled trials, the following adverse reactions were reported in ≥2% and greater than placebo of Zepbound-treated adult patients (excluding hypoglycemia): (frequencies listed, respectively, as: placebo [N=958]; 5 mg [N=630]; 10 mg [N=948]; 15 mg [N=941]): nausea (8%, 25%, 29%, 28%), diarrhea (8%, 19%, 21%, 23%), vomiting (2%, 8%, 11%, 13%), constipation (5%, 17%, 14%, 11%), abdominal pain (5%, 9%, 9%, 10%), dyspepsia (4%, 9%, 9%, 10%), injection site reactions (2%, 6%, 8%, 8%), fatigue (3%, 5%, 6%, 7%), hypersensitivity reactions (3%, 5%, 5%, 5%), eructation (1%, 4%, 5%, 5%), hair loss (1%, 5%, 4%, 5%), gastroesophageal reflux disease (2%, 4%, 4%, 5%), flatulence (2%, 3%, 3%, 4%), abdominal distension (2%, 3%, 3%, 4%), dizziness (2%, 4%, 5%, 4%), hypotension (0%,

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1%, 1%, 2%). Percentages reflect the number of patients who reported at least 1 occurrence of the adverse reaction.

Gastrointestinal Adverse Reactions: In Zepbound clinical trials, gastrointestinal adverse reactions occurred more frequently among patients receiving Zepbound (5 mg 56%, 10 mg 56%, 15 mg 56%) than placebo (30%). More patients receiving Zepbound 5 mg (1.9%), Zepbound 10 mg (3.3%), and Zepbound 15 mg (4.3%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.5%). The majority of nausea, vomiting, and/or diarrhea events occurred during dose escalation and decreased over time.

Hypotension: In Zepbound clinical trials, hypotension occurred more frequently among patients taking Zepbound (1.6%) than patients taking placebo (0.1%). Hypotension was more frequently seen in Zepbound-treated patients on concomitant antihypertensive therapy (2.2%) compared to Zepbound-treated patients not on antihypertensive therapy (1.2%). Hypotension also occurred in association with gastrointestinal adverse events and dehydration.

Hypersensitivity Reactions: In Zepbound clinical trials, immediate hypersensitivity reactions (within one day after drug administration) occurred in 2.1% of Zepbound-treated patients compared to 0.4% of placebo-treated patients, while non-immediate hypersensitivity reactions occurred in 3.5% of Zepbound-treated patients compared to 2.7% of placebo-treated patients. Among Zepbound-treated patients, hypersensitivity reactions were more frequent in those with anti-tirzepatide antibodies (6.2%) compared to those who did not develop anti-tirzepatide antibodies (3%).The majority of the hypersensitivity reactions in trials were skin reactions (e.g., rash, itching).

Injection Site Reactions: In Zepbound-treated patients in clinical trials, injection site reactions were more frequent in those with anti-tirzepatide antibodies (11.3%) compared to those who did not develop anti-tirzepatide antibodies (1%).

Hair Loss: Hair loss adverse reactions in Zepbound-treated patients were associated with weight reduction. In Zepbound clinical trials, hair loss was reported more frequently in female than male patients in the Zepbound (7.1% female versus 0.5% male) and placebo (1.3% female versus 0% male) treatment groups. No Zepbound-treated patients and one placebo-treated patient discontinued study treatment due to hair loss.

Other Adverse Reactions:

Acute Kidney Injury: In clinical trials, acute kidney injury was reported in 0.5% of Zepbound-treated patients compared to 0.2% of placebo-treated patients.

Acute Gallbladder Disease: In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients.

Hypoglycemia: In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2 , hypoglycemia (plasma glucose <54 mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In a trial of obesity/overweight without type 2 diabetes mellitus, there was no systematic capturing of hypoglycemia, but plasma glucose <54 mg/dL was reported in 0.3% of Zepbound-treated patients versus no placebo-treated patients.

Heart Rate Increase: In Zepbound clinical trials, treatment with Zepbound resulted in a mean increase in heart rate of 1 to 3 beats per minute compared to no increase in placebo-treated patients.

Laboratory Abnormalities:

Amylase and Lipase Increase: In clinical trials, treatment with Zepbound resulted in mean increases from baseline in serum pancreatic amylase concentrations of 20% to 25% and serum lipase concentrations of 28% to 35%, compared to mean increases from baseline in pancreatic amylase of 2.1% and serum lipase of 5.8% in placebo-treated patients. The clinical significance of elevations in amylase or lipase with Zepbound is unknown in the absence of other signs and symptoms of pancreatitis.

Postmarketing Experience:

Anaphylaxis, angioedema, ileus

DRUG INTERACTIONS

Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin:

Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia.

Oral Medications:

Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound.

Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation. Hormonal contraceptives that are not administered orally should not be affected.

USE IN SPECIFIC POPULATIONS

Pregnancy:

Pregnancy Exposure Registry: There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Zepbound (tirzepatide) during pregnancy. Pregnant patients exposed to Zepbound and healthcare providers are encouraged to contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Risk Summary: Weight loss offers no benefit to a pregnant patient and may cause fetal harm. Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Zepbound when a pregnancy is recognized (see Clinical Considerations). Available data with tirzepatide in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. In pregnant rats administered tirzepatide during organogenesis, fetal growth reductions and fetal abnormalities occurred at clinical exposure in maternal rats based on AUC. In rabbits administered tirzepatide during organogenesis, fetal growth reductions were observed at clinically relevant exposures based on AUC. These adverse embryo/fetal effects in animals coincided with pharmacological effects on maternal weight and food consumption. The estimated background risk of major birth defects and miscarriage for the indicated population is increased when compared to the general population. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations:

Disease-Associated Maternal and/or Embryo/Fetal Risk: Appropriate weight gain based on pre-pregnancy weight is currently recommended for all pregnant patients, including those with obesity or overweight, due to the obligatory weight gain that occurs in maternal tissues during pregnancy.

Lactation: Risk Summary: There are no data on the presence of tirzepatide or its metabolites in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zepbound and any potential adverse effects on the breastfed infant from Zepbound or from the underlying maternal condition.

Females and Males of Reproductive Potential: Contraception: Use of Zepbound may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation.

Pediatric Use The safety and effectiveness of Zepbound have not been established in pediatric patients less than 18 years of age.

Geriatric Use: In Zepbound clinical trials, 226 (9%) Zepbound-treated patients were 65 years of age or older, and 13 (0.5%) Zepbound-treated patients were 75 years of age or older at baseline. No overall differences in safety or effectiveness of Zepbound have been observed between patients 65 years of age and older and younger adult patients.

Renal Impairment: No dosage adjustment of Zepbound is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no change in tirzepatide pharmacokinetics (PK) was observed. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Hepatic Impairment: No dosage adjustment of Zepbound is recommended for patients with hepatic impairment. In a clinical pharmacology study in subjects with varying degrees of hepatic impairment, no change in tirzepatide PK was observed.

OVERDOSE: In the event of an overdosage, contact the Poison Help Line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations. Appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A period of observation and treatment for these symptoms may be necessary, taking into account the half-life of tirzepatide of approximately 5 days.

PATIENT COUNSELING INFORMATION: Advise the patient to read the FDA-approved patient labeling *(Medication Guide and Instructions for Use)*.

Missed Doses: Inform patients if a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, inform patients to resume their regular once weekly dosing schedule.

Additional information can be found at www.Zepbound.lilly.com, at lillymedical.com, or by calling The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).

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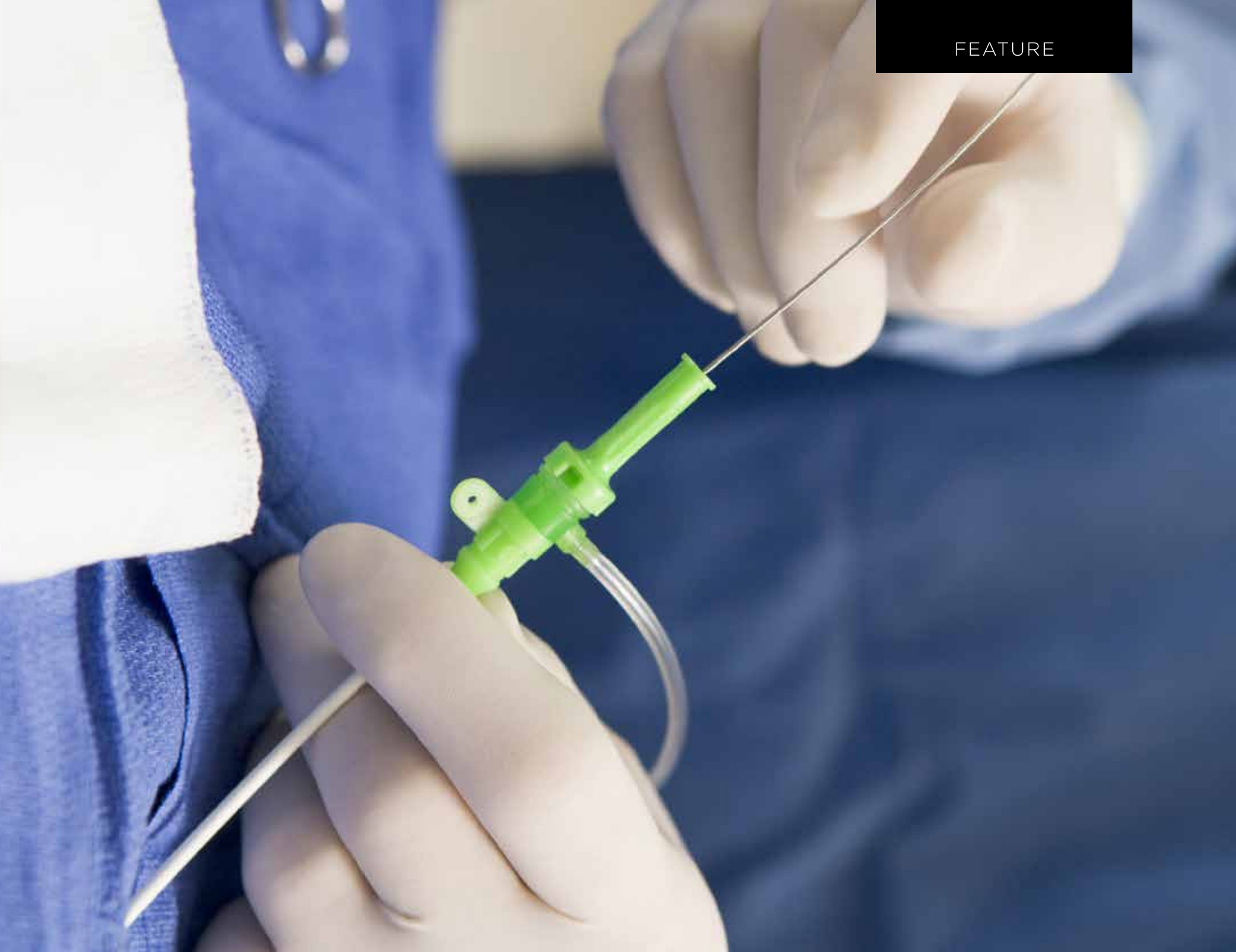
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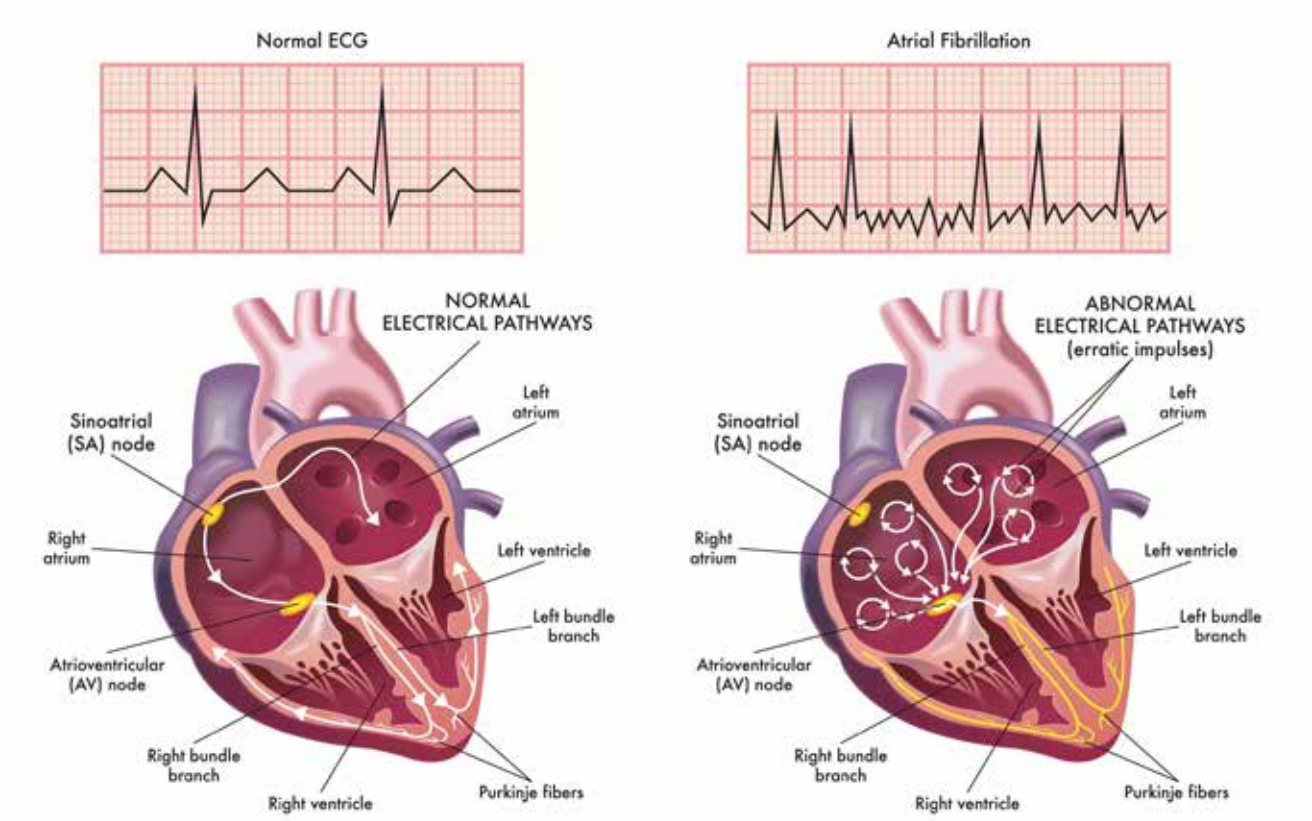
The Case for Cardiac Catheter Ablation First over Drug Treatment

BY AARON MEDARIS, PUBLISHER, PHYSICIANS OFFICE RESOURCE

Within the right atrium is a group of cells called the sinus node, the heart's natural pacemaker. It's here where signals are produced to start each heartbeat. When a heart is functioning properly, the signal travels from the sinus node through both atria, and through a pathway between the atria and ventricles known the atrioventricular node. This transmission of electrical signals allows the heart to contract and pump blood through the body.

But what happens when those electrical signals are not functioning properly? When faulty electrical signals are sent, a heart experiences arrhythmia, making the heartbeat too fast, too slow, or irregular in nature.

Atrial Fibrillation (AFib) is the most common type of heart arrythmia and occurs when the two atria of the heart beat in an irregular way thus inhibiting the flow of blood to the ventricles. Symptoms of AFib include irregular heartbeat, heart palpitations, lightheadedness, extreme fatigue, shortness of breath, and chest pain. Chronic AFib is a progressive disorder that can lead to heart failure and increases a person's risk for stroke. The CDC reports that AFib causes about 1 in 7 strokes.[1]



Today, an estimated 6 million people in the US suffer with atrial fibrillation. The CDC expects that number to grow to 12.1 million by the year 2030. In 2019 AFib was mentioned on 183,321 death certificates and was the underlying cause of death in 26,535 of those deaths.[1]

In this article we'll review current treatments for AFib including drug therapy and cardiac catheter ablation; in addition to new findings from a study published by the New England Journal of Medicine titled, "Progression of Atrial Fibrillation after Cryoablation or Drug Therapy" that focuses on the benefits of treating AFib patients with a cardiac catheter ablation rather than with drug therapy.

Drug Therapy

When a patient is first treated for AFib, they are often prescribed three types of medications to help prevent and control irregular heartbeats and stoke[2]:

- Heart rate controllers
- Heart rhythm controllers
- Blood Thinners

Heart Rate Controllers

Heart rate controllers usually consist of two different classes of drugs, Beta blockers and calcium channel blockers.

Beta Blockers are a class of drug that prevent the stimulation of the adrenergic receptors, thus blocking the effects of the hormone epinephrine (adrenaline). Because of this block, the heart begins to beat slower and with less force. Some examples of beta blockers include[2]:

- Metoprolol
- Propranolol
- Timolol
- Nadolol
- Atenolol
- Bisoprolol
- Carvedilol

Calcium Channel Blockers are medications that lower blood pressure by preventing calcium to enter the heart and artery cells. By blocking calcium and its effects of causing the heart and arteries to contract with greater force, heart rate slows and blood pressure lowers.

Depending on heath and conditions being treated, there are short-acting and long-acting forms of calcium channel blockers available. Short-acting medications work quicker but don't last very long. Long-acting medications release at a slower rate thus providing a longer lasting effect. Some examples of calcium blockers that are used to treat AFib include:

- Diltiazem
- Verapamil

Heart Rhythm Controllers

Known as a chemical/pharmacological cardioversion, heart rhythm controllers are drugs used to restore normal heart rhythm. Drugs used in this therapy fall in to two classifications: sodium channel blockers and potassium channel blockers.

Sodium Channel Blockers are a class I antiarrhythmic that inhibit sodium influx through cell membranes. This inhibition of sodium lowers the heart's ability to conduct electricity. Examples of this drug include:

- Flecainide
- Propafenone
- Quinidine

Potassium Channel Blockers are a Class III Antiarrhythmic that prolongs the action potential duration by inhibiting repolarizing potassium channel blockers.3 This prolongs the length of time that the cell is unexcitable. Examples of this drug include:

- Amiodarone
- Sotalol
- Dofetilide
- Dronedarone

Blood Thinners

Because blood clots and stroke are closely associated with AFib, physicians often prescribe blood thinners to reduce the risk of occurrence and damage caused by those conditions. Examples of blood thinners include:

- Warfarin
- Apixaban
- Dabigatran
- Edoxaban
- Rivaroxban

With the heart rate and rhythm controlled, most people begin to feel better. But what about disease progress? Yes, the medications are treating the symptoms of AFib, but the actual disease can still progress and affect other cells of the heart and AFib can return. Other treatment options for AFib include Electrical Cardioversion Therapy and Cardiac Ablation.

Electrical Cardioversion

Electrical cardioversion is a method in which the heart rhythm is rest by sending electric shocks through the heart. Even with electrical cardioversion, patients are often still prescribed heart rate and rhythm controllers and blood thinners to help prevent future episodes.

Cardiac Ablation

Normally last in line in the treatment of AFib, a cardiac catheter ablation involves utilizing heat or extreme cold to create a pattern of scars (known as a maze procedure) in the atria. Scar tissue does not send electrical signals, so the scars act as barriers to the cells that are sending rogue signals that cause AFib.

The Case for Cardiac Catheter Ablation First over Drug Treatment

As mentioned previously, a cardiac catheter ablation is often last in line in treatment of patients with AFib. However, a recent study published in the New England Journal of Medicine titled, "Progression of Atrial Fibrillation after



Cryoablation or Drug Therapy," concluded that treating patients with cardiac catheter ablation first rather than with drugs can stop the disease from getting worse.4

Dr. Jason G. Andrade, principle investigator of the study said, "If we perform the procedure earlier, the thinking was that maybe we could change that disease trajectory. We could prevent people from having these more advanced forms of atrial fibrillation, and so the procedure will not only work better, but it will change how people are living with the disease and lead to a much better long-term outcomes"[5]

Their study included two randomized groups out of a cohort of 303 people who were treated for AFib to compare the disease progression. One group would be treated with medicine first and the second group would receive a cardiac catheter ablation first. Patients of both groups received an implanted cardiac monitor after treatment to track changes over a three-year period.

One of the most striking findings of this study showed a 75% reduction in the progression of AFib in patients who received a cardiac catheter ablation over those who only received drug treatment. Dr. Andrade went on to say, "By doing the procedure, you really got at the source of the problem and prevented people from developing more advanced forms of the disease over several years of follow-up. We know that the more advanced forms of atrial fibrillation have higher rates of stroke, are more likely to cause heart failure, and result in premature mortality. We've now shown for the first time that an intervention in the form of catheter ablation changes the disease trajectory and prevents patients from going on to have those more advanced forms of atrial fibrillation."[5]

The study also showed that patients who received the ablation experienced fewer serious adverse events at a rate of 4.5% compared to those who received only drug treatment at 10.1%.

This is the second of such a study performed on treating AFib with a catheter ablation over drug therapy. The authors of this study suggested that more research on the topic will be coming.

Drug therapy will always be essential in the treatment of AFib. However, based on this study's findings, I believe this will help flip the trend to patients receiving cardiac catheter ablations sooner rather than later.

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OSOM® COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for prescription use only. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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1. Sillesen, H., & Falk, E. (2011). Peripheral artery disease (PAD) screening in the asymptomatic population: why, how, and who?. Current atherosclerosis reports, 13(5), 390–395. https://doi.org/10.1007/s11883-011-0196-x
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



3520

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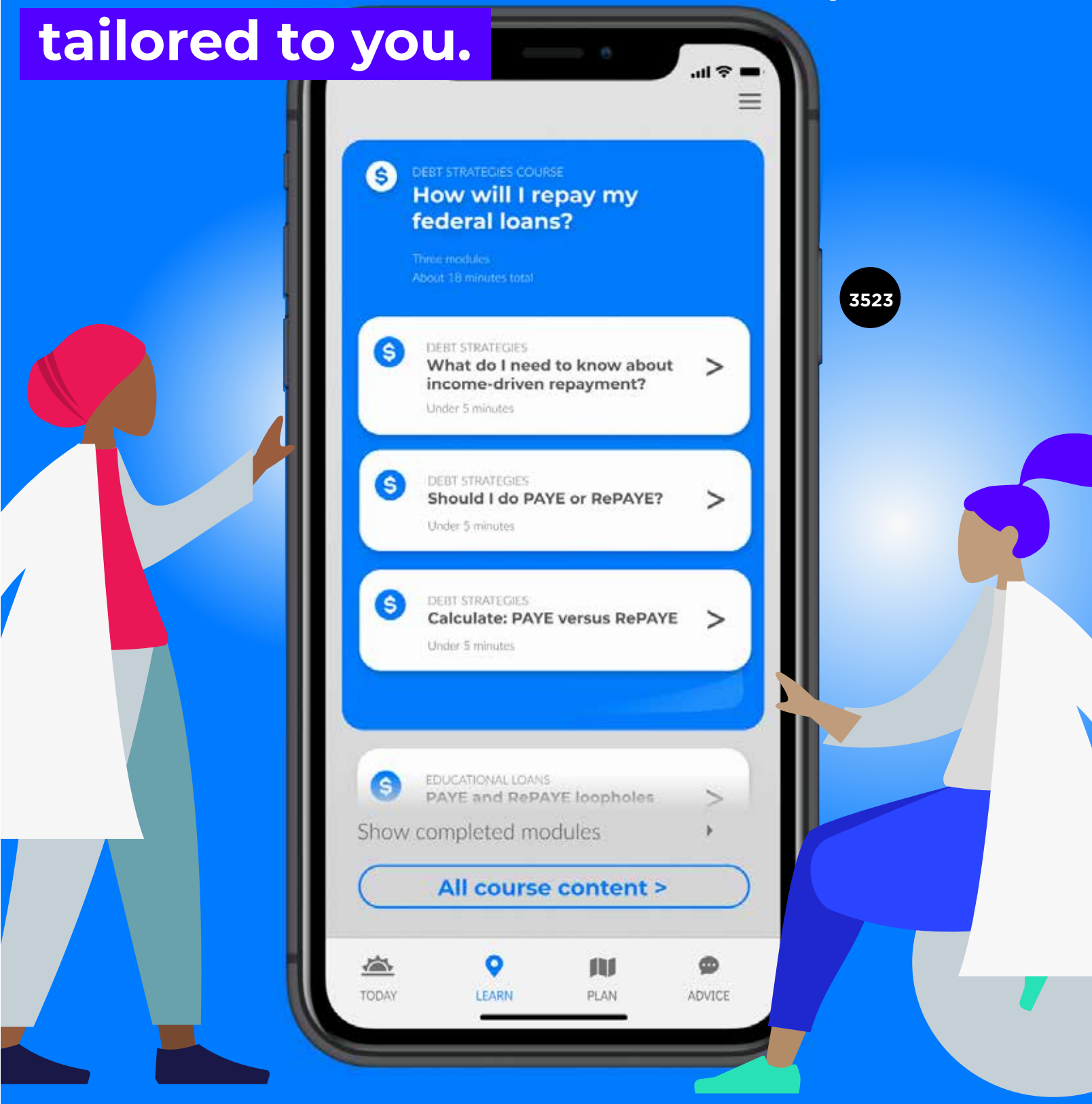
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Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes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

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BIOFIRE SPOTFIRE

From bioMerieux

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2 ANS Testing

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- **Reimburses $170/test using 3 CPT codes**
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3 SudoMotor Testing

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PERIPHERAL ARTERIAL DISEASE



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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.

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PAD TESTING SYSTEMS IDEAL FOR PRIMARY CARE TO VASCULAR SPECIALISTS

from Newman Medical

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The simpleABI Cuff-Link System is Easy to Learn and Use.

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2024 TOP TRAVEL TRENDS AND DESTINATIONS

BY JEN HELMLE



As the post-Covid world continues to evolve and adapt in the wake of global changes, the travel industry is no exception. The year 2024 is shaping up to be an exciting one for travel enthusiasts, with emerging trends reflecting a blend of technology, sustainability, and unique cultural experiences. Some unavoidable financial truths will also be at the forefront of your travel planning this year. This article explores the top travel trends and destinations for 2024, offering insights into what the future of travel holds.

Dollars and Cents

A few forecasts that are based on hard data like advance bookings or future contracts are fairly reliable. In 2024:

- Domestic airfares will fall. Airfares will slide 16 percent this year compared to 2023 for U.S. flights, according to Kayak. The average round-trip ticket will cost $461. Internationally, fares will rise 10 percent from last year.

- Car rental rates will climb. American Express projects car rental prices will increase by 5 percent this year in the U.S. and Canada. But some destinations, such as Mexico, won't see any change in prices.

- Fuel prices will drop. Gas prices will slide almost 5 percent, to an average of $3.36 in 2024, according to projections from the U.S. Energy Information Administration. That should make spring break and summer driving trips more affordable.

- Hotel rates will rise. Lodging rates will increase almost 7 percent on average in 2024, according to research by BCD Travel. But it will vary by city and time of year.

Overall, travel should be affordable in 2024, barring any big surprises. But it depends on where you go and when you go.

If you're traveling to Europe, you could spend $8 a gallon on gas. And an affordable hotel room in Paris will be out of the question this July. Average hotel rates during the Olympic Games are up from $187 a night to $764, according to the Paris Tourist Office.

Personalized and Tech-Enhanced Experiences

The demand for personalized travel experiences is on the rise. Travelers in 2024 are seeking trips that are tailored to their preferences, from accommodation to activities. Technology plays a crucial role in this, with AI and machine learning algorithms being used to offer personalized recommendations and itineraries. Moreover, the use of virtual reality (VR) and augmented reality (AR) in travel is becoming more prevalent, allowing tourists to explore destinations virtually before they even pack their bags.

Sustainable and Responsible Travel

Sustainability continues to be a significant focus in 2024. Travelers are increasingly conscious of their environmental impact and are seeking sustainable travel options. This includes eco-friendly accommodations, carbon offsetting initiatives, and support for local communities. Destinations that prioritize sustainability, such as Costa Rica and Iceland, are becoming particularly popular.

Off-the-Beaten-Path Destinations

There's a growing trend towards exploring less-known destinations. Travelers in 2024 are looking to escape the crowds and experience something unique. This has led to the popularity of destinations like Georgia (the country), Madagascar, and Mongolia, known for their unspoiled landscapes and rich cultural heritage.

Wellness and Health-Conscious Travel

The wellness travel trend will continue to flourish in 2024. More travelers are choosing destinations based on wellness retreats, spa experiences, and health-oriented activities. This trend also includes a focus on mental health, with an increase in 'digital detox' vacations where guests disconnect from technology to focus on relaxation and rejuvenation.

Adventure and Active Travel

Adventure travel is reaching new heights in 2024. Destinations offering unique outdoor experiences, such as Patagonia for trekking and New Zealand for bungee jumping, are in high demand. This trend caters to travelers looking for an adrenaline rush as well as those seeking to challenge themselves physically and mentally.

Culinary and Gastronomy Experiences

Culinary tourism continues to be a major draw in 2024. Travelers are not just looking to taste local cuisine but also to learn about the culture and history behind it. Destinations renowned





for their food scenes, like Italy, Japan, and Mexico, are attracting food enthusiasts who are eager to participate in cooking classes, food tours, and farm-to-table experiences.

Multi-Generational and Family Travel

There's an increasing trend in multi-generational family travel. Families are looking for destinations that offer activities and experiences suitable for all ages. This includes family-friendly resorts, educational tours, and activities that can be enjoyed collectively, fostering bonding and creating lifelong memories.

Solo and Female-Only Travel

Solo travel, especially among women, is on the rise. This has led to the development of services and tours catering specifically to solo and female travelers, focusing on safety, community, and unique experiences. Destinations like Scandinavia and Japan, known for their safety and ease of travel, are popular among solo female travelers.

Cultural and Immersive Experiences

Travelers in 2024 are seeking authentic and immersive cultural experiences. This includes staying in local homes, participating in cultural workshops, and exploring off-the-beaten-path locations. Countries rich in history and culture, such as Peru, India, and Morocco, are attracting travelers looking to deepen their understanding and appreciation of different cultures.
Luxury and Exclusivity

The luxury travel market continues to grow, with travelers seeking exclusive and high-end experiences. This includes luxury cruises, private jet travel, and stays in exclusive resorts or private islands. Destinations like the Maldives, Monaco, and Seychelles remain popular for those seeking luxury and privacy.



TOP 10 DESTINATIONS FOR 2024

1. Bhutan
Bhutan stands out as a beacon of sustainability and cultural preservation. Its policy of high-value, low-impact tourism ensures an exclusive experience amidst majestic Himalayan landscapes and rich Buddhist culture.

2. Kyoto, Japan
Kyoto offers a stunning mix of Japan's rich history and modern luxury. Known for its temples, traditional tea houses, and the annual cherry blossom season, Kyoto is a cultural gem that offers an authentic Japanese experience.

3. Patagonia, Chile/Argentina
Straddling Chile and Argentina, Patagonia is a paradise for adventurers. Its rugged, remote landscapes encompass towering mountains, massive glaciers, and sprawling steppe, making it ideal for trekking, kayaking, and wildlife watching.

4. Maldives
A perennial favorite, the Maldives is synonymous with luxury. Its overwater bungalows, pristine beaches, and private island resorts offer an exclusive escape for those seeking relaxation and water-based activities in a tropical paradise.

5. Santorini, Greece
Famous for its dramatic views, stunning sunsets, and white-washed buildings, Santorini is a romantic and luxurious getaway. The island's boutique hotels and private villas provide a perfect backdrop for a serene vacation.

6. Tuscany, Italy
Tuscany is a destination that combines natural beauty with cultural richness. Its rolling hills, vineyards, and historic cities like Florence and Siena offer a quintessential Italian experience with luxury villas, fine wines, and gourmet dining.

7. Rwanda
Emerging as a luxury destination, Rwanda offers a unique wildlife experience. The chance to see mountain gorillas in their natural habitat, combined with upscale lodges and exclusive tours, makes it an ethical and unforgettable journey.

8. Dubai, UAE
A city of superlatives, Dubai offers an extravagant blend of modern architecture, luxury shopping, and world-class dining. Its lavish hotels, desert safaris, and cultural experiences provide a diverse range of activities for luxury travelers.

9. Paris, France
The timeless elegance of Paris continues to attract luxury travelers. With its world-renowned fashion, art, and culinary scenes, Paris offers an experience of sophistication and romance that remains unparalleled.

10. Antarctica
For those seeking a truly unique adventure, Antarctica is a once-in-a-lifetime destination. Luxury cruises to this remote continent offer an opportunity to witness its extraordinary wildlife and surreal landscapes in an exclusive setting.



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

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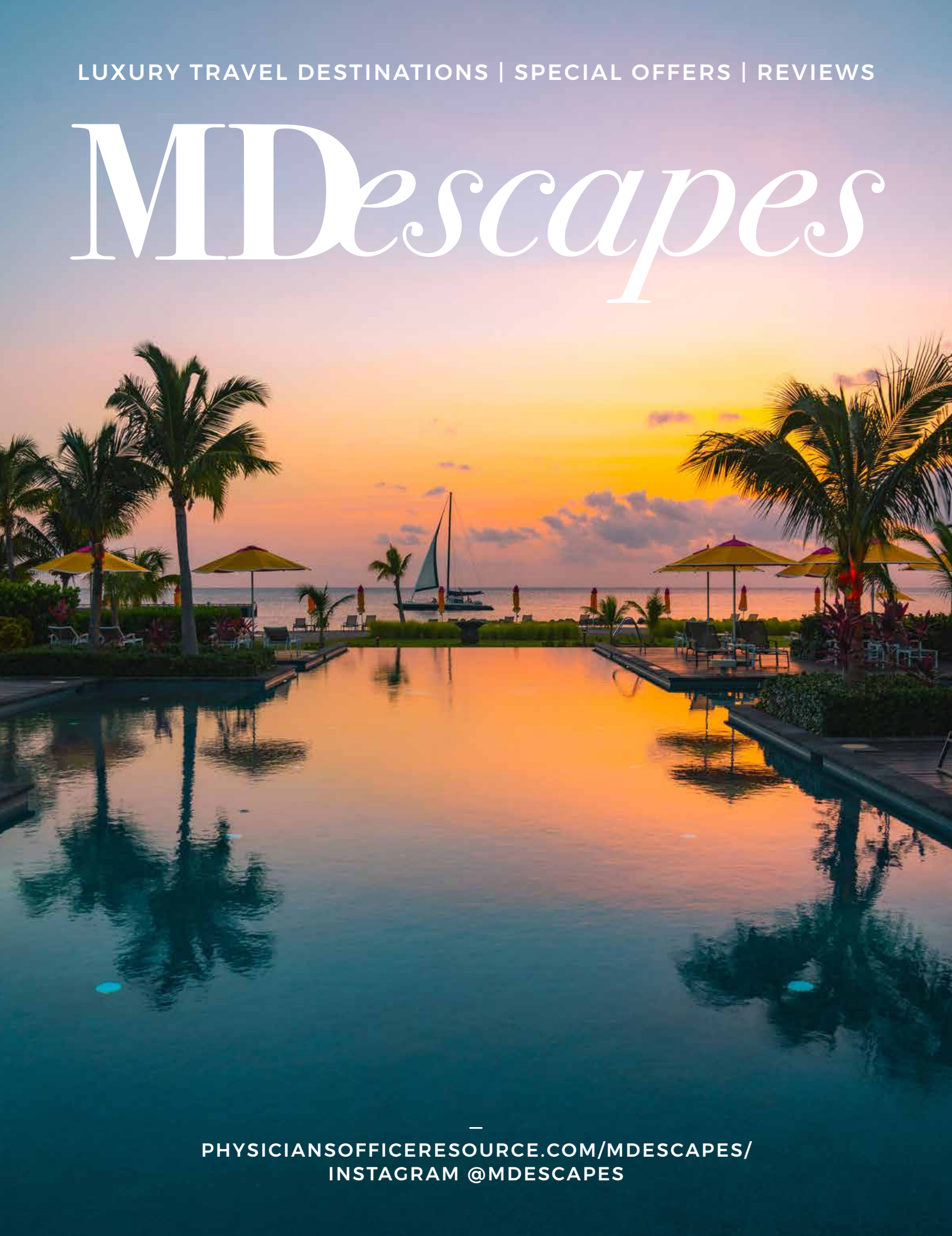
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The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test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

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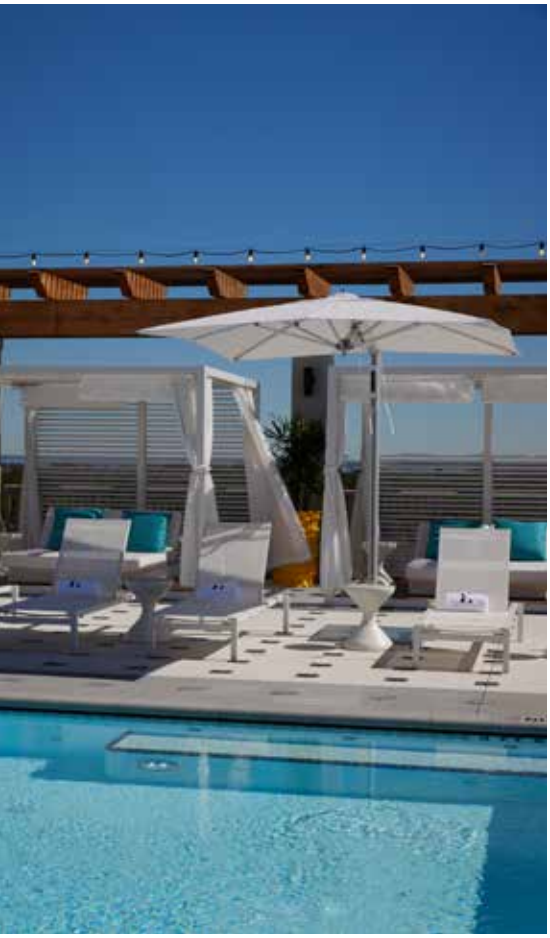
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