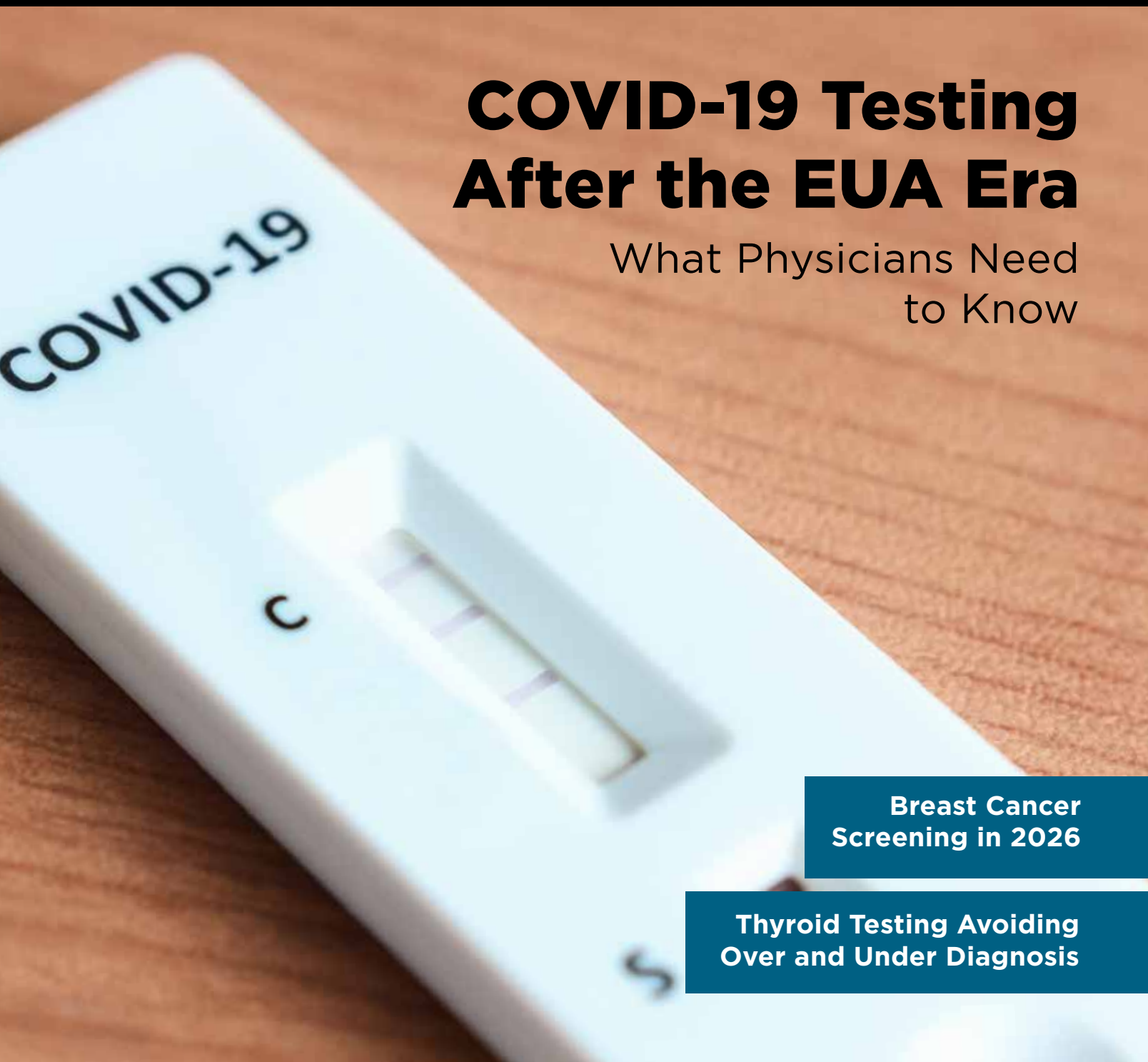
2026 | Issue 10

Physicians office Resource

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COVID-19 Testing After the EUA Era

What Physicians Need to Know

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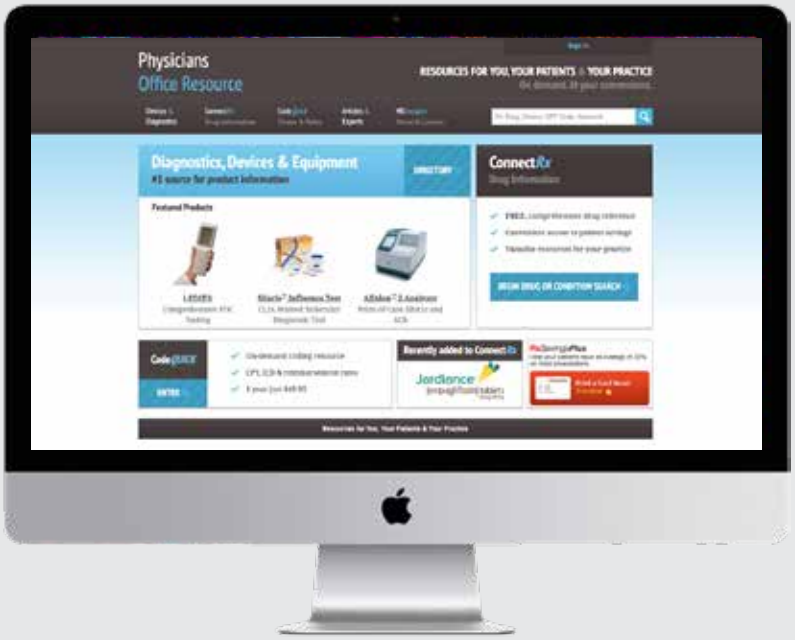
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These tests have not been FDA cleared or approved. They are authorized by FDA under an EUA for use by authorized laboratories. The emergency use of these products is only authorized for the duration of the declaration that circumstances exist justifying 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. § 360bbb 3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

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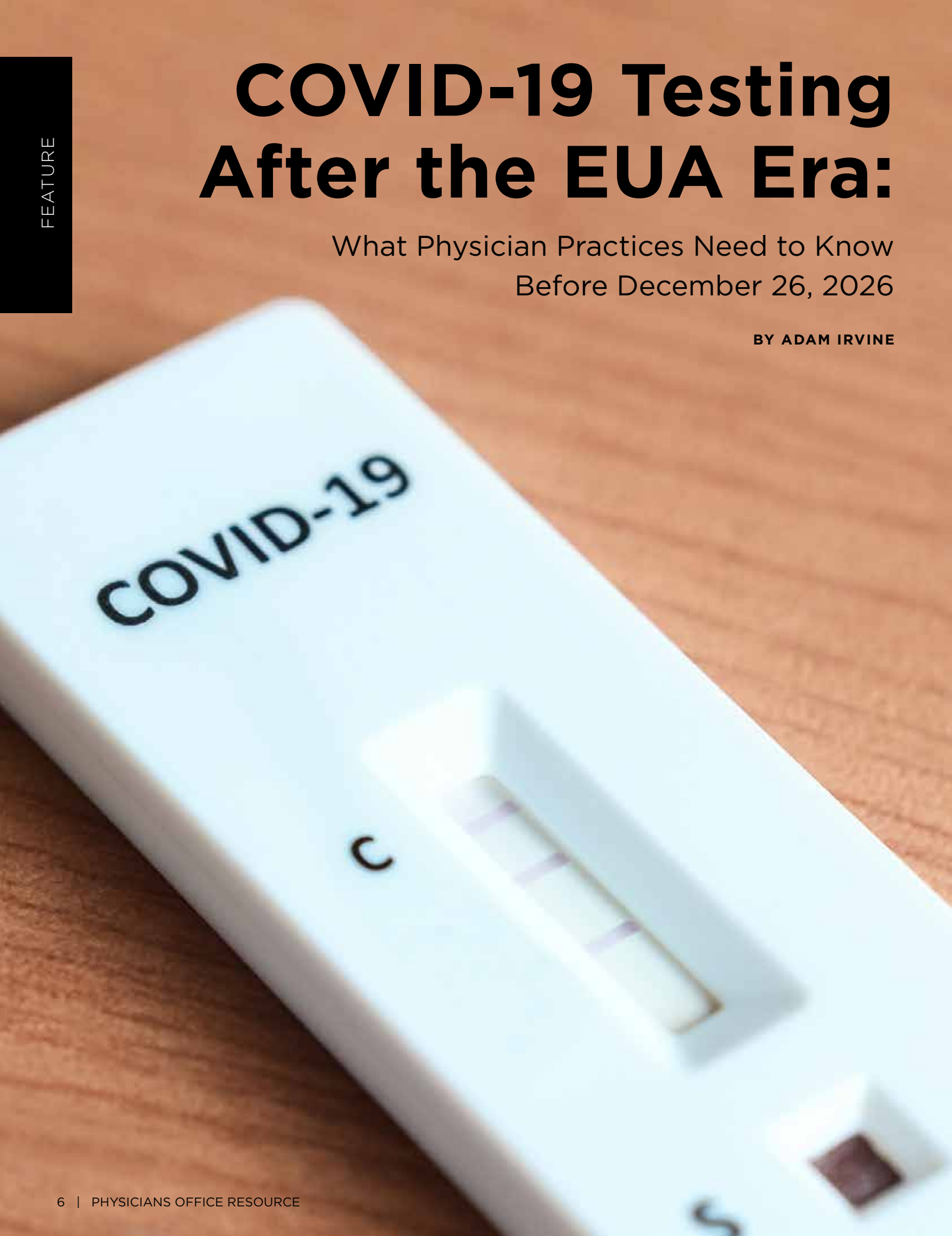
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FEATURE

COVID-19 Testing After the EUA Era:

What Physician Practices Need to Know Before December 26, 2026

BY ADAM IRVINE



For nearly seven years, Emergency Use Authorizations helped make COVID-19 diagnostic tests widely available across the United States. That regulatory chapter is now approaching its conclusion. On December 26, 2026, the federal declarations supporting Emergency Use Authorizations for SARS-CoV-2 diagnostic tests and other COVID-19 medical devices will terminate.

For physician offices, urgent care centers, laboratories, and other testing sites, the deadline requires attention—but it does not mean that COVID-19 testing is ending. Instead, it marks a transition from emergency authorization to the traditional regulatory pathways used for other diagnostic products.

Practices should begin reviewing their testing platforms, inventory, laboratory certifications, and vendor communications now. Waiting until respiratory-virus season is underway could create avoidable disruptions in testing availability and patient care.

What Is Changing?

On June 29, 2026, the Secretary of the U.S. Department of Health and Human Services determined that the circumstances justifying emergency authorization of COVID-19 medical devices no longer exist. HHS subsequently announced that three device-related EUA declarations would terminate after a 180-day transition period, effective December 26, 2026.

The affected declarations cover:

- In vitro diagnostic tests used to detect or diagnose SARS-CoV-2
- Personal respiratory protective devices authorized during the COVID-19 outbreak
- Other medical devices, including alternative products used as medical devices because of pandemic-related shortages

When the declarations terminate, COVID-19 diagnostic products that remain authorized solely under an EUA will no longer have that federal authorization. This includes affected molecular, antigen, serology, and other in vitro diagnostic products unless the manufacturer has obtained traditional FDA marketing authorization or another applicable legal status.

The transition is broader than the withdrawal of a few individual products. It ends the underlying declaration that allowed FDA to issue and maintain device EUAs for COVID-19.

The deadline for drugs and biological products is different. The EUA declaration supporting COVID-19 drugs and biological products is scheduled to terminate on June 29, 2027. The December 2026 deadline specifically applies to diagnostic tests and other medical devices.

COVID-19 Testing Is Not Ending

The most important distinction for practices is that the end of the EUA declaration is not a prohibition on COVID-19 testing.

Tests that have received traditional FDA clearance, approval, or other appropriate marketing authorization may continue to be marketed and used according to their labeling. Manufacturers that originally entered the market through an EUA have had the opportunity to submit their products through FDA's established premarket review pathways.

These pathways generally require a more complete regulatory submission than an EUA. Depending on the device, a manufacturer may pursue authorization through a 510(k), de novo, or premarket approval pathway. FDA's review considers the test's analytical and clinical performance, manufacturing controls, labeling, intended use, and other factors.

As a result, the post-EUA marketplace will likely contain fewer COVID-19 tests, but the products that remain will have completed a conventional regulatory review. Some manufacturers may successfully transition their tests before the deadline, while others may discontinue products rather than invest in the additional regulatory process.

Physician practices should not assume that a familiar test will remain available simply because it has been used successfully for several years.

EUA Status and CLIA Status Are Different

The transition may be especially important for physician-office laboratories operating under a CLIA Certificate of Waiver.

FDA authorization and CLIA categorization serve different purposes. FDA determines whether a diagnostic device may be legally marketed for its stated intended use. CLIA requirements determine where and by whom laboratory testing may be performed based on the test's complexity.

During the pandemic, many point-of-care and over-the-counter tests were distributed under EUAs that permitted use in settings operating under a CLIA Certificate of Waiver. The termination of those EUAs means practices must confirm that their replacement products possess both the necessary FDA marketing authorization and a CLIA status appropriate for the setting in which they will be used.

A test receiving FDA clearance does not automatically mean that every version, specimen type, or intended-use setting is CLIA waived. Practices should review the current instructions for use and FDA documentation for the precise product configuration they intend to purchase.

This is particularly important for combination tests. A multiplex assay detecting SARS-CoV-2 along with influenza A, influenza B, respiratory syncytial virus, or other pathogens may have a different regulatory status from a manufacturer's COVID-only product. One product in a vendor's portfolio may be traditionally authorized while another remains available solely under an EUA.

What Happens to Existing Inventory?

Practices should not assume they may continue using EUA-only tests after December 26 merely because the products were

purchased before the deadline or have not reached their printed expiration dates.

An expiration date describes the period during which the manufacturer supports the product's stability and performance. It does not independently authorize the test's continued use after the legal authority supporting its distribution and use has ended.

FDA or HHS may issue additional product-specific transition, disposition, or enforcement guidance before the deadline. Until that information is available, practices should avoid building excess inventory of any test that relies solely on an EUA.

Manufacturers and distributors should be asked to provide written confirmation regarding:

- The product's current FDA status
- Whether it remains authorized solely under an EUA
- Whether a traditional marketing submission has been filed
- Whether FDA has granted clearance or approval
- The product's CLIA complexity classification
- Instructions for unused inventory remaining after December26
- Availability of a traditionally authorized replacement

Verbal assurances from a sales representative should not substitute for current regulatory documentation.

Preparing the Physician Office Laboratory

A structured inventory review is the best place to begin. Practices should document the manufacturer, exact product name, catalog number, lot number, expiration date, specimen type, and current regulatory status of every COVID-19 test in use or storage.

The practice should then verify each product directly through FDA resources and manufacturer documentation. Similar product names can create confusion, particularly when a manufacturer markets multiple versions of an assay for laboratory, point-of-care, or home use.

Medical directors and laboratory leaders should also evaluate how a product change may affect the clinical workflow. Questions may include whether a replacement test uses the same specimen type, whether collection procedures differ, how long results take, and whether new instrumentation or quality-control materials will be required.

Additional considerations include:

- Updating standard operating procedures
- Training and documenting the competency of testing personnel
- Revising quality-control and quality-assurance processes
- Updating electronic health record order and result codes
- Confirming billing and payer requirements
- Revising patient instructions and educational materials
- Planning for confirmation or reflex testing when appropriate
- Coordinating changes with affiliated laboratories and distributors

Practices should preserve the authorization documents and instructions for use that applied while an EUA product was being used. These records may remain important for laboratory compliance, quality investigations, and interpretation of historical patient results.

Clinical Testing Still Matters

The end of emergency authorization should not be interpreted as evidence that SARS-CoV-2 has disappeared or that diagnostic testing no longer has clinical value. COVID-19 continues to circulate, and its symptoms overlap substantially with influenza, RSV, and other respiratory infections.

Testing can still influence antiviral treatment decisions, infection-control recommendations, counseling for high-risk household contacts, evaluation of vulnerable patients, and decisions about additional testing. Its value is greatest when the result is likely to change management and when the test is selected and interpreted in the context of symptom duration, specimen quality, pretest probability, and local disease activity.

Rapid antigen tests may offer speed and convenience, but a negative result does not always exclude infection, particularly early in the course of illness. Molecular assays generally provide greater analytical sensitivity, although their availability, turnaround time, and cost may differ. The regulatory transition does not change these fundamental principles of diagnostic stewardship.

Moving From Emergency Access to Routine Regulation

The December 26 deadline represents the maturation of the COVID-19 diagnostic market. Emergency authorization allowed tests to reach patients quickly when approved or cleared alternatives were limited and the public-health need was extraordinary. Traditional authorization is intended to provide a more durable regulatory foundation for continued use.

For physician practices, the transition should be treated as an operational deadline rather than a reason for alarm. The essential questions are straightforward: Which tests does the practice currently use? Which remain dependent on an EUA? Which have obtained traditional authorization? Are they appropriate for the practice's CLIA certificate and intended testing environment?

Practices that answer those questions early will be positioned to maintain access to reliable COVID-19 testing without interrupting patient care. Those that wait until late December may face depleted inventory, limited replacement options, rushed staff training, and confusion about which products may legally be used.

December 26, 2026, will not end COVID-19 testing. It will end the emergency regulatory framework that shaped the testing market during the pandemic—and move COVID-19 diagnostics into a more conventional, permanent phase of laboratory medicine.

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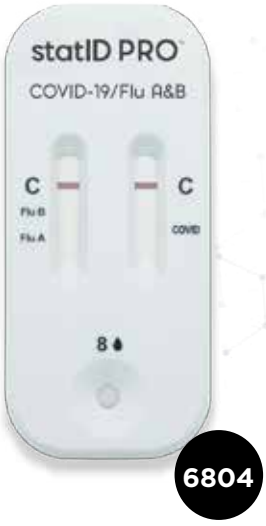
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FOR YOUR PATIENTS WITH OVERACTIVE BLADDER (OAB)...[1]



INDICATIONS AND USAGE

GEMTESA® is a beta-3 adrenergic agonist indicated for the treatment of:

- overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.
- overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of GEMTESA. Hypersensitivity reactions, such as angioedema, have occurred.

WARNINGS AND PRECAUTIONS

Urinary Retention

Urinary retention has been reported in patients taking GEMTESA. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for the treatment of OAB. Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction or patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

Angioedema

Angioedema of the face and/or larynx has been reported with GEMTESA. Angioedema has been reported to occur hours after the first dose or after multiple doses. Angioedema, associated with upper airway swelling, may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, immediately discontinue GEMTESA and provide appropriate therapy and/or measures necessary to ensure a patent airway.

More than 1 million patients have turned to GEMTESA for their OAB treatment[2]*

THERE IS ONLY ONE GEMTESA– NO GENERIC SUBSTITUTE[3]

THE FIRST & ONLY β_3-AGONIST WITH[1]...



PROVEN RESULTS TO HELP YOUR PATIENTS STRIKE AGAINST ALL 3 KEY SYMPTOMS OF OAB — INCLUDING MALE PATIENTS BEING TREATED FOR BPH[1,4†]

- The 3 key symptoms of OAB are **urgency, frequency, and urge urinary incontinence (UUI)**[1,4]
- Only GEMTESA is proven to treat OAB symptoms in men being pharmacologically treated for BPH[1]



AN OPTION FOR HYPERTENSIVE PATIENTS[1,5‡§]

- No clinically significant impact on hypertension or blood pressure[1,5,6]
- In a 24-week study of OAB in men being treated for BPH, rates of hypertension were 9.0% with GEMTESA (n=553) vs 8.3% with placebo (n=551)[1]



NO DRUG INTERACTION WITH CYP2D6 SUBSTRATES[1,2]

- Concomitant use of GEMTESA increases digoxin maximal concentrations (C_{max}) and systemic exposure as assessed by area under the concentration-time curve (AUC). Serum digoxin concentrations should be monitored before initiating and during therapy with GEMTESA and used for titration of the digoxin dose to obtain the desired clinical effect. Continue monitoring digoxin concentrations upon discontinuation of GEMTESA and adjust digoxin dose as needed[1]



- Most common adverse reactions (≥2%) reported with GEMTESA were headaches, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection[1]

*Based on new US prescriptions filled through February 2026.[2]

†The efficacy of GEMTESA was evaluated in a pivotal 12-week, double-blind, randomized, placebo- and active-controlled trial in patients with OAB (UUI, urgency, and urinary frequency). For study entry, patients had to have symptoms of OAB for at least 3 months with an average of 8 or more micturitions per day and at least 1 UUI per day, or an average of 8 or more micturitions per day and an average of at least 3 urgency episodes per day. A total of 1515 patients received at least 1 daily dose of placebo (n=540), GEMTESA 75 mg (n=545), or an active-control treatment (n=430). The majority of patients were Caucasian (78%) and female (85%) with a mean age of 60 (range 18 to 93) years.[1]

‡In a 12-week pivotal study, hypertension rates for OAB patients taking GEMTESA (n=545) were 1.7% vs 1.7% with placebo (n=540). Increased BP rates were 0.7% with GEMTESA vs 0.9% with placebo.[6]

§In a 4-week, randomized, placebo-controlled, ambulatory BP study in OAB patients (n=200), daily treatment with GEMTESA 75 mg was not associated with clinically significant changes in BP. Mean age 59 years; 75% female. At baseline: 35% of subjects had preexisting hypertension; 29% of subjects were taking at least 1 concomitant antihypertensive medication.[1]

BP=blood pressure; BPH=benign prostatic hyperplasia.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

Most common adverse reactions (≥2%) reported with GEMTESA were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

Please see accompanying Brief Summary on the following pages.

References: 1. GEMTESA. Prescribing Information. Marlborough, MA; Sumitomo Pharma America; 2025. **2.** Data on file. Sumitomo Pharma America, Inc. **3.** *Approved Drug Products With Therapeutic Equivalence Evaluations.* 44th Edition. US Dept of Health and Human Services; 2024. **4.** Edmondson SD, Zhu C, Kar NF, et al. Discovery of vibegron: a potent and selective β_3 adrenergic receptor agonist for the treatment of overactive bladder. *J Med Chem.* 2016;59(2):609-623. doi:10.1021/acs.jmedchem.5b01372 **5.** Weber MA, Haag-Molkenteller C, King J, Walker A, Mudd PN Jr, White WB. Effects of vibegron on ambulatory blood pressure in patients with overactive bladder: results from a double-blind, placebo-controlled trial. *Blood Press Monit.* 2022;27(2):128-134. doi:10.1097/MBP.0000000000000572 **6.** Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN Jr. International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: EMPOWUR. *J Urol.* 2020;204(2):316-324. doi:10.1097/JU.0000000000000807

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GEMTESA® (vibegron) 75 mg tablets

BRIEF SUMMARY—Please see the GEMTESA® package insert for full Prescribing Information.

GEMTESA®
(vibegron) 75 mg tablets

INDICATIONS AND USAGE

GEMTESA® is a beta-3 adrenergic agonist indicated for the treatment of:
• overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.
• overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH).

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of GEMTESA. Hypersensitivity reactions, such as angioedema, have occurred.

WARNINGS AND PRECAUTIONS

Urinary Retention: Urinary retention has been reported in patients taking GEMTESA. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for the treatment of OAB. Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction or patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

Angioedema: Angioedema of the face and/or larynx has been reported with GEMTESA. Angioedema has been reported to occur hours after the first dose or after multiple doses. Angioedema, associated with upper airway swelling, may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, immediately discontinue GEMTESA and provide appropriate therapy and/or measures necessary to ensure a patent airway. GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any component of GEMTESA.

ADVERSE REACTIONS

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.

Overactive Bladder in Adults: The safety of GEMTESA was evaluated in a 12-week, double-blind, placebo- and active-controlled study (Study 3003) in patients with OAB. A total of 545 patients received GEMTESA. The majority of the patients were White (78%) and female (85%) with a mean age of 60 years (range 18 to 93 years).

Adverse reactions that were reported in Study 3003 at an incidence greater than placebo and in ≥2% of patients treated with GEMTESA are as follows:

Adverse Reactions, Exceeding Placebo Rate, Reported in ≥2% of Patients Treated with GEMTESA 75 mg for up to 12 Weeks in Study 3003

	GEMTESA 75 mg n (%)	Placebo n (%)
Number of Patients	**545**	**540**
Headache	22 (4.0)	13 (2.4)
Nasopharyngitis	15 (2.8)	9 (1.7)
Diarrhea	12 (2.2)	6 (1.1)
Nausea	12 (2.2)	6 (1.1)
Upper respiratory tract infection	11 (2.0)	4 (0.7)

Other adverse reactions reported in <2% of patients treated with GEMTESA included:

Gastrointestinal disorders: dry mouth, constipation
Investigations: residual urine volume increased
Renal and urinary disorders: urinary retention
Vascular disorders: hot flush

GEMTESA was also evaluated for long-term safety in an extension study (Study 3004) in 505 patients who completed the 12-week study (Study 3003). Of the 273 patients who received GEMTESA 75 mg once daily in the extension study, 181 patients were treated for a total of one year.

Adverse reactions reported in ≥2% of patients treated with GEMTESA 75 mg for up to 52 weeks in the long-term extension study, and not already listed above, were urinary tract infection (6.6%) and bronchitis (2.9%).

Overactive Bladder in Adult Males with BPH: The safety of GEMTESA was evaluated in a 24-week double-blind, randomized, placebo-controlled study (Study 3005) in male patients with OAB on pharmacological therapy for BPH. A total of 553 patients received GEMTESA.

Adverse reactions that were reported in Study 3005 at an incidence greater than placebo and in ≥2% of patients treated with GEMTESA are as follows:

Adverse Reactions, Exceeding Placebo Rate, Reported in ≥2% of Patients Treated with GEMTESA 75 mg for up to 24 Weeks in Study 3005

	GEMTESA 75 mg n (%)	Placebo n (%)
Number of Patients	**553**	**551**
Hypertension*	50 (9.0)	46 (8.3)
Urinary tract infection	14 (2.5)	12 (2.2)

*Defined as average systolic blood pressure (SBP) ≥140mmHg or diastolic BP (DBP) ≥90mmHg on 3 assessments at two consecutive visits, in non-hypertensive patients.
*Defined as an average increase of SBP ≥20mmHg or DBP≥10mmHg on 3 assessments at two consecutive visits, or the initiation or increase in dose of antihypertensive medications at any visit, in hypertensive patients.

GEMTESA was also evaluated for long-term safety in a 28-week extension study (Study 3006) in 276 patients who completed the 24-week study (Study 3005). Of the 276 patients who received GEMTESA 75 mg once daily in the extension study, 124 patients were treated for a total of one year.

There were no additional adverse reactions reported in Study 3006 that are not already included above.

POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during post-approval use of vibegron. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following adverse events have been reported in association with vibegron use in worldwide postmarketing experience:

Urologic disorders: urinary retention
Skin and subcutaneous tissue disorders: angioedema of the face and larynx; hypersensitivity reactions, including urticaria, pruritus, rash and drug eruption; eczema
Gastrointestinal disorders: constipation

DRUG INTERACTIONS

Concomitant use of GEMTESA increases digoxin maximal concentrations (C_{max}) and systemic exposure as assessed by area under the concentration-time curve (AUC). Serum digoxin concentrations should be monitored before initiating and during therapy with GEMTESA and used for titration of the digoxin dose to obtain the desired clinical effect. Continue monitoring digoxin concentrations upon discontinuation of GEMTESA and adjust digoxin dose as needed.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary There are no available data on GEMTESA use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

In animal studies, no effects on embryo-fetal development were observed following administration of vibegron during the period of organogenesis at exposures approximately 275-fold and 285-fold greater than clinical exposure at the recommended daily dose of GEMTESA, in rats and rabbits, respectively. Delayed fetal skeletal ossification was observed in rabbits at approximately 898-fold clinical exposure, in the presence of maternal toxicity. In rats treated with vibegron during pregnancy and lactation, no effects on offspring were observed at 89-fold clinical exposure. Developmental toxicity was observed in offspring at approximately 458-fold clinical exposure, in the presence of maternal toxicity. No effects on offspring were observed at 89-fold clinical exposure (see Data).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies carry some risk of birth defect, loss, or other adverse outcomes. 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.

Data Animal Data In an embryo-fetal developmental toxicity study, pregnant rats were treated with daily oral doses of 0, 30, 100, 300, or 1000 mg/kg/day vibegron during the period of organogenesis (Days 6 to 20 of gestation). These doses were associated with systemic exposures (AUC) 0-, 9-, 89-, 275-, and 1867-fold higher, respectively, than in humans treated with the recommended daily dose of GEMTESA. No embryo-fetal developmental toxicity was observed at doses up to 300 mg/kg/day. Treatment with the high dose of 1000 mg/kg/day was discontinued due to maternal toxicity.

In an embryo-fetal developmental toxicity study, pregnant rabbits were treated with daily oral doses of 0, 30, 100, or 300 mg/kg/day vibegron during the period of organogenesis (Days 7 to 20 of gestation). These doses were associated with systemic exposures (AUC) 0-, 86-, 285-, and 898-fold higher, respectively, than in humans treated with the recommended daily dose of GEMTESA. No embryo-fetal developmental toxicity was observed at doses of vibegron up to 100 mg/kg/day. Maternal toxicity (decreased food consumption), reduced fetal body weight, and an increased incidence of delayed skeletal ossification, were observed at 300 mg/kg/day.

In a pre- and post-natal developmental toxicity study, pregnant or lactating rats were treated with daily oral doses of 0, 30, 100, or 500 mg/kg/day vibegron from day 6 of gestation through day 20 of lactation. These doses were associated with estimated systemic exposures (AUC) 0-, 9-, 89-, and 458-fold higher, respectively, than in humans treated with the recommended daily dose of GEMTESA. No developmental toxicity was observed in F1 offspring at doses up to 100 mg/kg/day. Maternal toxicity was observed during lactation (decreased body weight gain) at doses ≥100 mg/kg/day and during gestation (decreased body weight gain and food consumption) at 500 mg/kg/day. Developmental toxicity was observed in F1 offspring (increased stillborn index, lethality, reduced viability and weaning indices, decreased body weight and body weight gains, low physical development differentiation indices, and effects on sensory function and reflexes) at 500 mg/kg/day.

Lactation: Risk Summary There are no data on the presence of vibegron in human milk, the effects of the drug on the breastfed infant, or the effects on milk production. When a single oral dose of radiolabeled vibegron was administered to postnatal nursing rats, radioactivity was observed in milk *(see Data)*. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for GEMTESA and any potential adverse effects on the breastfed infant from GEMTESA or from the underlying maternal condition.

Data Animal Data In a lactational transfer study, lactating rats were treated with a single oral dose of 10 mg/kg radiolabeled [^{3}H] vibegron on postpartum day 10. Levels of radioactivity were determined in milk and plasma collected at 1, 4, 12, and 24 after dosing. The C_{max} of total radioactivity in milk and plasma were observed at 9 and 2 hours after dosing, respectively, with a maximum milk-to-plasma concentration ratio of 2.2 observed at 12 hours after dosing. Vibegron elimination from milk showed a similar trend as that from plasma. The radioactivity concentration in milk at 24 hours after administration was approximately 25% of the C_{max}.

Pediatric Use: The safety and effectiveness of GEMTESA in pediatric patients have not been established.

Geriatric Use: Of 526 patients who received GEMTESA in the clinical studies for OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency, 242 (46%) were 65 years of age or older, and 75 (14%) were 75 years of age or older. No overall differences in safety or effectiveness of GEMTESA have been observed between patients 65 years of age and older and younger adult patients.

Of the total number of GEMTESA-treated patients in clinical studies for OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH), 347 (63%) were 65 years of age and older, while 100 (18%) were 75 years of age and older. No overall differences in safety of GEMTESA have been observed between patients 65 years of age and older and younger adult patients.

Renal Impairment: No dosage adjustment for GEMTESA is recommended for patients with mild, moderate, or severe renal impairment (eGFR 15 to <90 mL/min/1.73 m^2). GEMTESA has not been studied in patients with eGFR <15 mL/min/1.73 m^2 (with or without hemodialysis) and is not recommended in these patients.

Hepatic Impairment: No dosage adjustment for GEMTESA is recommended for patients with mild to moderate hepatic impairment (Child-Pugh A and B). GEMTESA has not been studied in patients with severe hepatic impairment (Child-Pugh C) and is not recommended in this patient population.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity was observed in long-term studies conducted in mice and rats treated with daily oral doses of vibegron for approximately 2 years. In the mouse carcinogenicity study, CD-1 mice were treated with daily oral doses of vibegron up to 90 mg/kg/day in males and up to 150 mg/kg/day in females, corresponding to estimated systemic exposures (AUC) 21- and 55-fold higher, respectively, than in humans treated with the recommended daily dose of GEMTESA. In the rat carcinogenicity study, Sprague Dawley rats were treated with daily oral doses of vibegron up to 30 mg/kg/day in males and up to 180 mg/kg/day in females, corresponding to systemic exposures (AUC) 18- and 117-fold higher, respectively, than in humans treated with the recommended daily dose of GEMTESA.

Vibegron was not mutagenic in *in vitro* microbial reverse mutation assays, showed no evidence of genotoxic activity in an *in vitro* human peripheral blood lymphocyte chromosomal aberration assay, and did not increase the frequency of micronucleated polychromatic erythrocytes in an *in vivo* rat bone marrow micronucleus assay.

In fertility/general reproductive toxicity studies conducted in rats, females were treated with daily oral doses of 0, 30, 100, 300, or 1000 mg/kg/day vibegron and males were treated with daily oral doses of 0, 10, 30, or 300 mg/kg/day vibegron. No effects on fertility were observed in female or male rats at doses up to 300 mg/kg/day, associated with systemic exposure (AUC) at least 274-fold higher than in humans treated with the recommended daily dose of GEMTESA. General toxicity, decreased fecundity, and decreased fertility were observed in female rats at 1000 mg/kg/day, associated with estimated systemic exposure 1867-fold higher than in humans treated with the recommended daily dose of GEMTESA.

PATIENT COUNSELING INFORMATION Advise the patient to read the FDA-approved patient labeling (Patient Information).

Urinary Retention: Inform patients that GEMTESA has been associated with urinary retention. Inform patients that the risk of urinary retention may be increased in patients taking muscarinic antagonist medications for the treatment of OAB. Instruct patients to contact their healthcare provider if they experience symptoms consistent with urinary retention while taking GEMTESA.

Angioedema: Inform patients that GEMTESA may cause angioedema. Advise patients to immediately discontinue GEMTESA and seek medical attention if angioedema associated with upper airway swelling occurs as this may be life-threatening.

Administration Instructions: Advise patients that GEMTESA tablets can be swallowed whole with a glass of water or may be crushed, mixed with a tablespoon of applesauce and taken immediately with a glass of water.

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Breast Cancer Screening in 2026:

TURNING EVOLVING GUIDANCE INTO EFFECTIVE PRIMARY CARE

BY MATT BAKER, PHYSICIANS OFFICE RESOURCE

Breast cancer screening often begins with a brief conversation during a busy office visit. Its effectiveness, however, depends on decisions that extend well beyond ordering a mammogram: identifying elevated risk, choosing an appropriate interval, explaining breast density, and ensuring that abnormal findings reach diagnostic resolution. Primary care physicians connect these steps, often across multiple clinicians and health systems.

In 2026, that responsibility includes interpreting new guidance from the American College of Physicians (ACP) and new randomized evidence on artificial intelligence (AI) in mammography. Neither development eliminates disagreement among professional organizations. The practical challenge is to translate evolving recommendations into a documented, individualized plan that patients understand and can complete.

Screening in the 40s: A New 2026 Point of Disagreement

The US Preventive Services Task Force (USPSTF) recommendation remains biennial mammography for average-risk women aged 40 through 74. Issued in 2024, it carries a B recommendation and remains the current final guidance as of this article's review date. The USPSTF considers both digital mammography and digital breast tomosynthesis (DBT) effective screening modalities.[1]

A substantive 2026 update comes from ACP. Its April guidance recommends biennial mammography for asymptomatic, average-risk women aged 50 through 74. For those aged 40 through 49, ACP recommends discussing individual risk, benefits, and harms before deciding whether to screen. This differs from the USPSTF's routine screening recommendation beginning at 40. ACP emphasizes false-positive findings, psychological distress, overdiagnosis, overtreatment, additional testing, and radiation exposure in its assessment.[2]

Other organizations continue to recommend different schedules. The American College of Radiology (ACR) recommends annual mammography beginning at 40. The American Cancer Society (ACS) offers annual screening at ages 40 through 44, recommends it at ages 45 through 54, and allows annual or biennial screening thereafter.[3,4]

Physicians should explain these differences without leaving patients to choose among competing headlines. A useful discussion identifies the guideline informing the recommendation, the patient's risk profile, and her preferences concerning earlier detection and additional testing. The conversation should end with a clear next screening date. A vague instruction to "consider mammography" can become an unintended delay.

Risk Assessment Should Precede the First Mammogram

Age-based screening is appropriate only after considering whether the patient belongs in a higher-risk pathway. ACR recommends breast cancer risk assessment by age 25, particularly emphasizing Black women and women of Ashkenazi Jewish ancestry. This is an earlier recommendation that remains relevant in 2026, rather than a newly introduced requirement.[3]

Risk assessment should capture family history on both maternal and paternal sides, relatives' ages at diagnosis, known pathogenic variants, prior chest irradiation, and previous breast biopsy findings. An electronic record entry stating only "family history positive" provides little help in selecting screening or determining whether a genetics referral is warranted.

ACR recommends MRI surveillance beginning at ages 25 to 30 for several high-risk groups, including women with genetics-based risk, calculated lifetime risk of at least 20%, or chest irradiation at a young age. Mammography starting ages vary with the risk category.[3] A high-risk referral should therefore produce a specific imaging schedule rather than a generic instruction to begin screening early.

Hereditary cancer assessment also has a distinct purpose. The USPSTF recommends using an appropriate brief familial risk tool when personal history, family history, or ancestry suggests BRCA-related susceptibility, followed by genetic counseling when indicated. It recommends against routine genetic risk assessment or testing when these features are absent.5 Estimating breast cancer risk and assessing inherited susceptibility are related tasks, but their questions and downstream decisions differ.

For office workflow, the goal is a risk assessment that can be retrieved and updated. Record the tool used, relevant inputs, resulting estimate, and clinical action. Revisit the assessment when a relative receives a new diagnosis or additional biopsy information becomes available. A previously reassuring estimate should not become a permanent designation.

Dense Breasts: Translate Notification Into a Plan

Federal breast-density notification requirements took effect September 10, 2024. They are established policy in 2026, not a new screening guideline. Mammography reports describe density, while patient summaries indicate whether breast tissue is dense and explain its implications. Heterogeneously dense and extremely dense breasts comprise the dense categories.6

Two messages matter clinically: dense tissue can obscure cancer on mammography, and density itself is associated with increased cancer risk. Patients need both explanations. Notification alone may generate anxiety without clarifying whether the screening plan should change.

Recommendations for additional imaging remain divided. The USPSTF finds insufficient evidence to determine the balance of benefits and harms of supplemental ultrasound or MRI following an otherwise negative mammogram in women with dense breasts. An insufficient-evidence statement does not establish that these tests are ineffective.[1]

ACR recommends MRI for women with dense breasts who desire supplemental screening. In contrast, ACP's 2026 guidance advises against supplemental screening MRI or ultrasound in asymptomatic, average-risk women with dense breasts and advises considering supplemental DBT.[2,3] These recommendations should not be extrapolated to patients with hereditary susceptibility or other high-risk indications.

The practical response is to consider density alongside the complete risk profile and consult breast imaging when the appropriate pathway is uncertain. Document the rationale for additional imaging—or for continuing mammography alone—and explain the possibility of additional recalls or biopsies. Ensure patients understand whether the proposed examination addresses a screening risk or evaluates an existing abnormality.

Choosing Imaging Without Overpromising

DBT is increasingly familiar to patients as "3D mammography." It obtains images across the breast that allow radiologists to examine tissue in reconstructed slices. Studies suggest improved cancer detection and fewer callbacks compared with conventional 2D mammography. However, improved detection should not be equated automatically with a demonstrated reduction in breast cancer mortality.[4,7]

Supplemental MRI is an important component of many high-risk pathways, but it is not a universal replacement for mammography. ACS recommends that screening MRI, when indicated, accompany mammography because either modality may detect cancers missed by the other.[4]

The order should communicate the clinical purpose. An asymptomatic patient undergoing routine screening differs from a patient with a palpable abnormality or an unresolved imaging finding. Providing symptoms, prior results, and the reason for examination helps the imaging team select an appropriate diagnostic approach. Availability matters, but a patient should not lose access to timely mammography while waiting indefinitely for a preferred technology.

New for 2026: Randomized Evidence on AI-Assisted Mammography

The Swedish Mammography Screening with Artificial Intelligence (MASAI) trial reported its interval-cancer analysis in The Lancet in January 2026. More than 105,000 women were randomized to AI-supported screening or standard double reading without AI. AI helped direct examinations to single or double radiologist reading and provided detection support.[8]

Interval cancer rates were 1.55 per 1,000 participants with AI support and 1.76 per 1,000 with standard reading. The AI strategy met the prespecified noninferiority criterion; the difference did not establish statistically significant superiority for reducing interval cancers. Sensitivity was higher with AI support—80.5% versus 73.8%—while specificity was 98.5% in both groups.[8]

These findings strengthen evidence for AI as a tool within a radiologist-led screening program. They do not demonstrate a breast cancer mortality benefit or establish that every commercial AI system performs similarly. The Swedish double-reading setting also requires consideration when applying the findings to US practice.

For referring physicians, the implication is to evaluate the quality of the imaging service, including how new technology is implemented and monitored. AI availability alone is insufficient reason to alter screening intervals, omit indicated supplemental imaging, or reassure a patient with persistent symptoms after negative screening.

Screening Is Incomplete Until Abnormal Findings Are Resolved

The Breast Imaging Reporting and Data System (BI-RADS) provides a framework for follow-up. Category 0 indicates that additional imaging evaluation is needed. Categories 1 and 2 generally return to routine screening. Category 3 commonly calls for short-interval follow-up, often at six months. Categories 4 and 5 require prompt attention to biopsy recommendations.[7]

An office should assign responsibility for tracking each unresolved result. Sending a portal message or entering an order does not establish that the next step occurred. A practical registry can record the recommended action, scheduled date, completion status, and final outcome. Escalation should address missed appointments and referrals that never generate a report.

Communication should be specific and proportionate. Explain that additional imaging does not necessarily indicate cancer, describe what the examination will clarify, and identify who will arrange it. Patients should know whom to contact if scheduling stalls. These steps can be particularly useful for patients who interpret a callback as a diagnosis and avoid further evaluation out of fear.

Screening pathways also should remain separate from symptom evaluation. A new lump or other concerning breast change warrants clinical assessment and an appropriate diagnostic pathway, even after recent negative screening. A routine future screening appointment should not substitute for evaluating a current complaint.[7]

Older Adults, Access, and the Primary Care Opportunity

Stopping screening requires attention to health status and patient goals. The USPSTF finds evidence insufficient for screening at age 75 or older. ACP's 2026 guidance recommends discussing discontinuation at 75 or with limited life expectancy. ACS supports continued screening in women in good health with an expected survival of at least 10 years.[1,2,4]

The discussion should include whether the patient would pursue diagnostic procedures and treatment if screening identified cancer. It is helpful to explain why recommendations are changing rather than simply removing mammography from the preventive-care checklist. Document the decision so another clinician does not restart or stop screening without its context.

Access deserves the same attention as modality selection. Ask about transportation, language needs, discomfort, scheduling constraints, and anticipated expense. The Women's Preventive Services Initiative recommends individualized navigation for breast screening and follow-up, including assistance with access, referrals, education, and support services. Its screening recommendation also recognizes indicated additional imaging and pathology as steps needed to complete the screening process.[9]

Practices can translate this principle into a named contact for patients who encounter barriers. Before ordering additional testing, clarify scheduling and coverage questions with the imaging center and payer rather than promising that every examination will be covered without cost sharing. Track completion across the entire pathway, including diagnostic follow-up. Breast cancer screening in 2026 combines established mammography recommendations, continuing disagreement about screening intensity, and emerging technology. Primary care physicians make these elements useful by assessing risk early, explaining choices clearly, and ensuring that each recommendation reaches completion. The most effective screening plan is one that fits the patient's risk and goals—and reliably connects detection with diagnosis and care.

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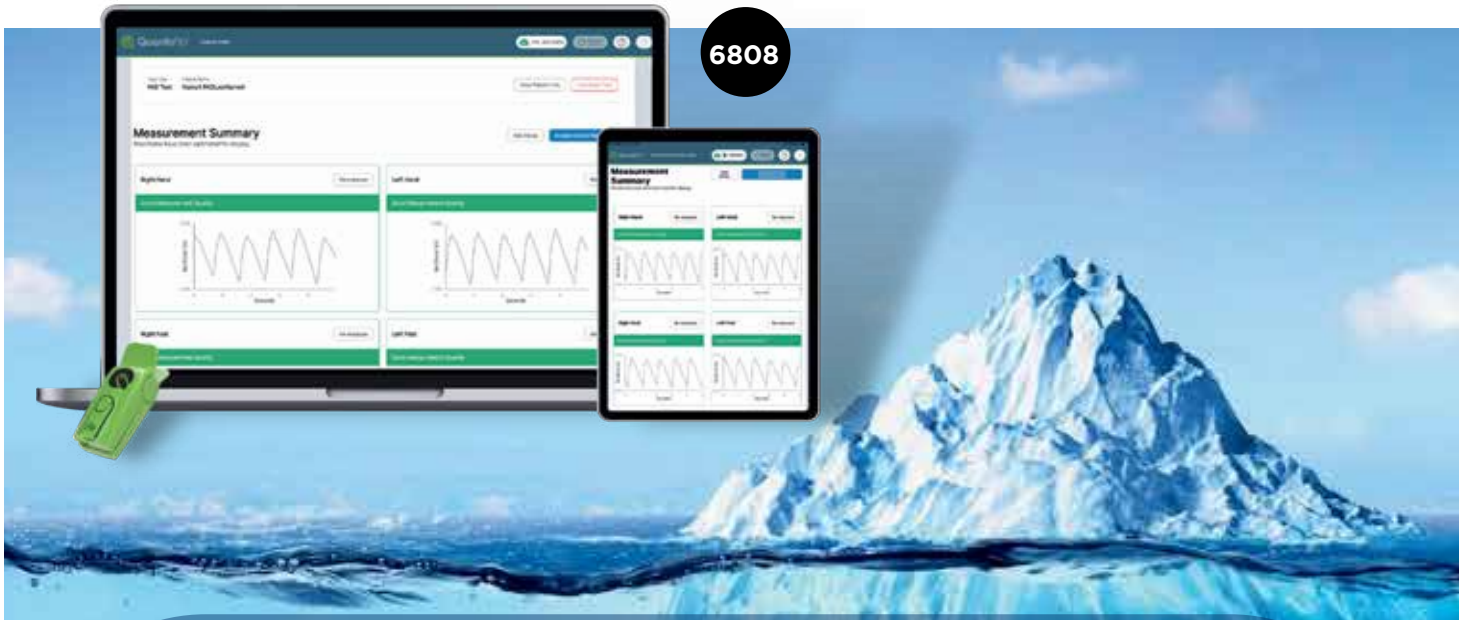
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1. BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 and Flu A+B. Package insert. 500051910 Becton, Dickinson and Company.

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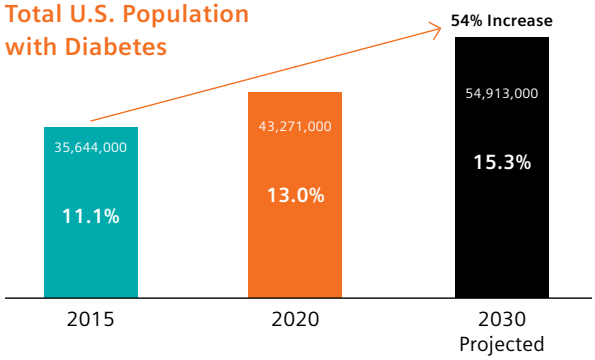
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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.

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1. BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 and Flu A+B. Package insert. 500051910 Becton, Dickinson and Company.

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Thyroid Testing:

Avoiding Over- and Under-Diagnosis

BY MATT BAKER, PHYSICIANS OFFICE RESOURCE

A patient arrives with fatigue, a few extra pounds, and a question that primary care physicians hear often: "Could it be my thyroid?"

It is a reasonable question. Thyroid disease can affect energy, weight, mood, bowel habits, and cardiovascular health. But those same complaints fill appointment schedules for reasons that have little to do with thyroid function. Poor sleep, medication effects, depression, and the demands of everyday life can produce a remarkably similar story.

Then the laboratory report arrives. TSH is slightly elevated. Free T4 is normal. The patient wants an answer, and the physician wants to help. Is this the explanation everyone has been looking for—or a finding that deserves a second look before it becomes a permanent diagnosis?

That is where thyroid testing becomes more than ordering a blood test. In primary care, the real work is deciding what the result means for the person sitting across the room.

Before the lab order, listen to the story

The ease of ordering TSH can make it feel like a natural addition to an annual laboratory panel. Yet routine screening and investigating suspected disease are different decisions. The US Preventive Services Task Force continues to find insufficient evidence to determine the balance of benefits and harms of screening asymptomatic, nonpregnant adults. That statement leaves room for judgment, but it does not establish a benefit from testing everyone.[1]

A clinical reason for testing gives the result a useful context. Fatigue alone is common. Fatigue accompanied by persistent cold intolerance, constipation, and other suggestive changes creates a stronger case. New atrial fibrillation, unexplained tachycardia, tremor, or weight loss should raise concern for excess thyroid hormone. Previous thyroid treatment, neck irradiation, autoimmune disease, and family history also help shape the decision.[1,2]

The history matters especially when disease presents quietly. An older adult with hyperthyroidism may show weight loss, weakness, or cardiac symptoms without the familiar picture of tremor and hyperactivity. Hypothyroid symptoms can disappear into an explanation of "getting older." A thoughtful approach avoids indiscriminate testing while keeping a treatable disorder on the differential.[3]

A small flag can carry a large meaning

Laboratory reports make abnormal results easy to spot. They do not make those results equally important. A TSH just outside the reference interval and a substantial elevation accompanied by low free T4 should lead to different conversations.

For most stable outpatients with suspected primary thyroid disease, TSH is a useful starting point. Reflex testing can add free T4 when TSH is elevated, and free T4 plus T3 when it is suppressed. Elevated TSH with low free T4 supports overt primary hypothyroidism; elevated TSH with normal free T4 defines subclinical hypothyroidism. Suppressed TSH with elevated free T4 or T3 indicates thyrotoxicosis.[4]

Those distinctions matter because the word "abnormal" can quickly become "disease," and "disease" can quickly become "medication." A reference interval helps interpret a measurement. It does not settle the treatment decision. TSH varies with physiology, age, illness, medications, and laboratory methods. Its distribution shifts upward with age, adding another reason to interpret a modest elevation carefully in an older patient.6

Imagine a 76-year-old with fatigue, TSH of 6.2 mIU/L, and normal free T4. The result deserves attention. It also leaves room for other explanations. Reviewing sleep, medications, recent illness, and the broader history while confirming the thyroid finding can prevent the first available answer from becoming the only answer considered.

Sometimes the best next step is another measurement

Repeating a borderline result can feel unsatisfying to a patient who hoped the first test would explain everything. But confirmation has a purpose: it distinguishes a persistent pattern from a temporary change.

For a stable, mild abnormality, reassessment after roughly two to three months is often reasonable, with timing adjusted to the clinical circumstances. More substantial abnormalities, worsening symptoms, or significant thyrotoxicosis require earlier evaluation. The point is to give a borderline finding enough context without allowing consequential disease to wait.1,2

The interval between tests is also an opportunity to review what might have influenced the result. Acute illness can alter thyroid hormone metabolism and TSH secretion, and recovery can produce temporary changes. Unless thyroid dysfunction is suspected as a contributor to the acute illness, testing during that period may create more confusion than clarity. An unexpected inpatient result may need reassessment after recovery.6,7

The supplement history deserves a direct question. Patients may not think to mention a hair, skin, and nail product when asked about medications. Biotin can interfere with susceptible assays, producing falsely low TSH and falsely elevated thyroid hormone measurements. That pattern can resemble hyperthyroidism even when thyroid function is normal. Coordinate repeat testing and any interruption of biotin with the laboratory, because the appropriate interval depends on dose, assay, and clearance.[4,6]

Amiodarone and lithium can cause genuine thyroid dysfunction; other medications can affect hormone metabolism, TSH secretion, or measurement. When the laboratory picture and the clinical picture do not fit, a conversation with the laboratory may be more useful than another prescription.[6]

The temptation to treat a number

Subclinical hypothyroidism puts the pressure to "do something" into sharp focus. The patient has symptoms, the test has a flag, and levothyroxine seems like a straightforward solution. Whether it will help is a separate question.

In the TRUST trial, 737 adults aged 65 or older with persistent subclinical hypothyroidism received levothyroxine or placebo. Treatment lowered TSH but did not improve hypothyroid symptom or tiredness scores at one year. The trial chiefly informs care of older adults with mild disease. It should not be used to dismiss overt hypothyroidism or applied wholesale to pregnancy or substantially greater TSH elevations.[8]

Treatment decisions should consider persistence, age, symptoms, reproductive status, and the degree of biochemical abnormality. As one guideline example, UK NICE guidance recommends considering levothyroxine for TSH of at least 10 mIU/L on two measurements three months apart. It also permits a six-month treatment trial in selected symptomatic adults younger than 65 with persistent elevations below 10. This is a framework for individualized decisions; recommendations differ across organizations and populations.[2]

Thyroid antibodies add another layer. A positive thyroid peroxidase antibody result can support autoimmune thyroiditis and help assess progression risk. It does not automatically mean the patient currently needs thyroid hormone. Repeating antibody levels generally adds little to ongoing management.[9]

For patients, that distinction can be difficult: "If I have Hashimoto's, why aren't we treating it?" Explaining that treatment replaces deficient hormone, while follow-up tracks whether deficiency develops, gives observation a clear purpose. A plan for reassessment is essential. Without it, watchful waiting can become a result that no one revisits.

Avoiding missed disease takes equal attention

Caution about treating a mildly elevated TSH should not make a persistently low TSH seem harmless. Normal free T4 does not end the evaluation when TSH is suppressed; T3 may reveal a different picture. Review thyroid hormone use, medications, and interference, then determine whether the suppression persists.[4,10]

A persistent TSH below 0.1 mIU/L deserves particular attention. ATA guidance recommends treatment of subclinical hyperthyroidism in adults aged 65 or older and in patients with relevant cardiac risk, heart disease, osteoporosis, or hyperthyroid symptoms. The cause matters: Graves disease, autonomous nodules, and thyroiditis do not all call for the same response.[10]

Thyroiditis, for example, may release stored hormone rather than increase hormone synthesis. Antithyroid drugs generally do not address that mechanism. Recognizing the difference avoids unnecessary therapy and helps anticipate a possible hypothyroid phase during recovery.[11]

There is also an important exception to the reassuring normal TSH. When pituitary disease is suspected, TSH alone can miss central hypothyroidism. Patients with pituitary disease, surgery, irradiation, or other suggestive findings need free T4 assessed alongside TSH. Low free T4 with an inappropriately normal, low, or mildly elevated TSH warrants further evaluation. Possible adrenal insufficiency must be assessed before starting levothyroxine in this setting.[5]

These exceptions are worth keeping in mind because under-diagnosis often begins with a result that appears reassuring when viewed alone.

More testing can create more questions

A larger thyroid panel is not necessarily a more informative one. T3 testing has a role in suspected hyperthyroidism, but rarely helps diagnose hypothyroidism. Reverse T3 does not provide a useful routine assessment of thyroid function in stable outpatients. Tests should earn their place by answering a clinical question.[4]

The same principle applies to ultrasound. An isolated abnormal TSH without a palpable abnormality or another structural indication should not routinely lead to imaging. Incidental nodules can start a sequence of surveillance and procedures without explaining the original complaint. Conversely, a normal TSH does not exclude a clinically important nodule. A concerning neck examination needs an appropriate structural evaluation.[12]

Keeping function and structure distinct helps the physician explain why one patient needs blood testing, another needs imaging, and some need both.

Pregnancy changes the conversation

Pregnancy deserves its own approach. Changes in gestational physiology affect thyroid test interpretation, and decisions require pregnancy-specific reference ranges and monitoring. Known thyroid disease should be reviewed before conception when possible and promptly when pregnancy is identified.[13]

The ATA published updated guidance in 2026 addressing preconception, pregnancy, and postpartum thyroid disease. Primary care physicians should use that framework with obstetric and endocrine colleagues. Postpartum thyroiditis also deserves consideration when fatigue and mood changes persist; those symptoms can otherwise blend into the expected demands of caring for a newborn. Evidence supporting conservative management in older adults cannot simply be transferred to pregnancy.[13]

The conversation continues after the prescription

A thyroid diagnosis is not finished when treatment begins. Excess replacement creates its own problems, making follow-up part of responsible prescribing. Thyroid function is generally reassessed about six to eight weeks after levothyroxine initiation or dose changes. TSH usually guides treatment of primary hypothyroidism; central disease requires a different monitoring approach.[3,5,15]

Before increasing a dose for an unexpected TSH, ask how the medication is actually taken. Missed doses, food, calcium, and iron can affect exposure. Increasing the prescription and then correcting inconsistent administration can overshoot the intended replacement. Persistent symptoms despite appropriate biochemical treatment should also reopen the broader differential rather than repeatedly drive the dose upward.[14]

Patients deserve an explanation of what the results establish and what remains uncertain. "Your thyroid levels do not explain these symptoms" should be followed by a plan to investigate them. "We need to repeat this test" should come with a reason and a timeframe.

That is the balance primary care brings to thyroid testing: attention to the laboratory finding, attention to the patient's experience, and a plan that connects the two. Done well, the process helps prevent unnecessary diagnoses while giving meaningful thyroid disease the attention it needs.

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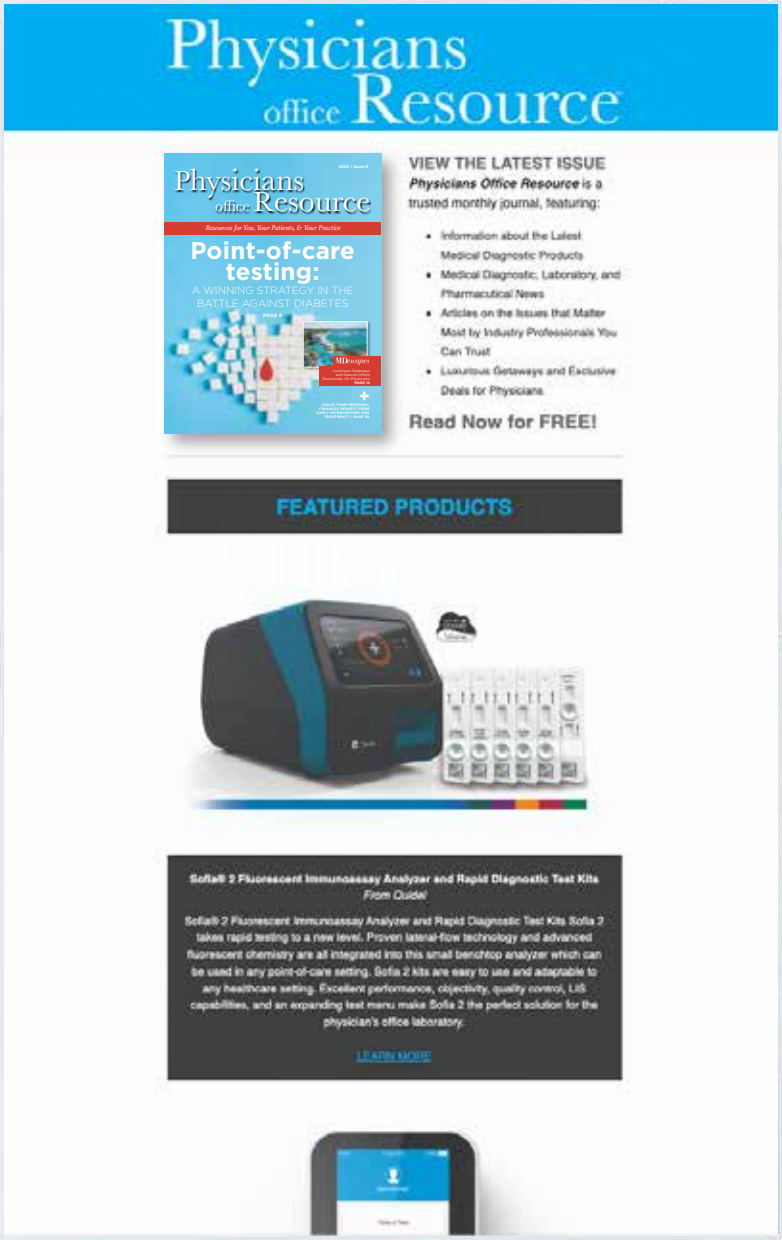
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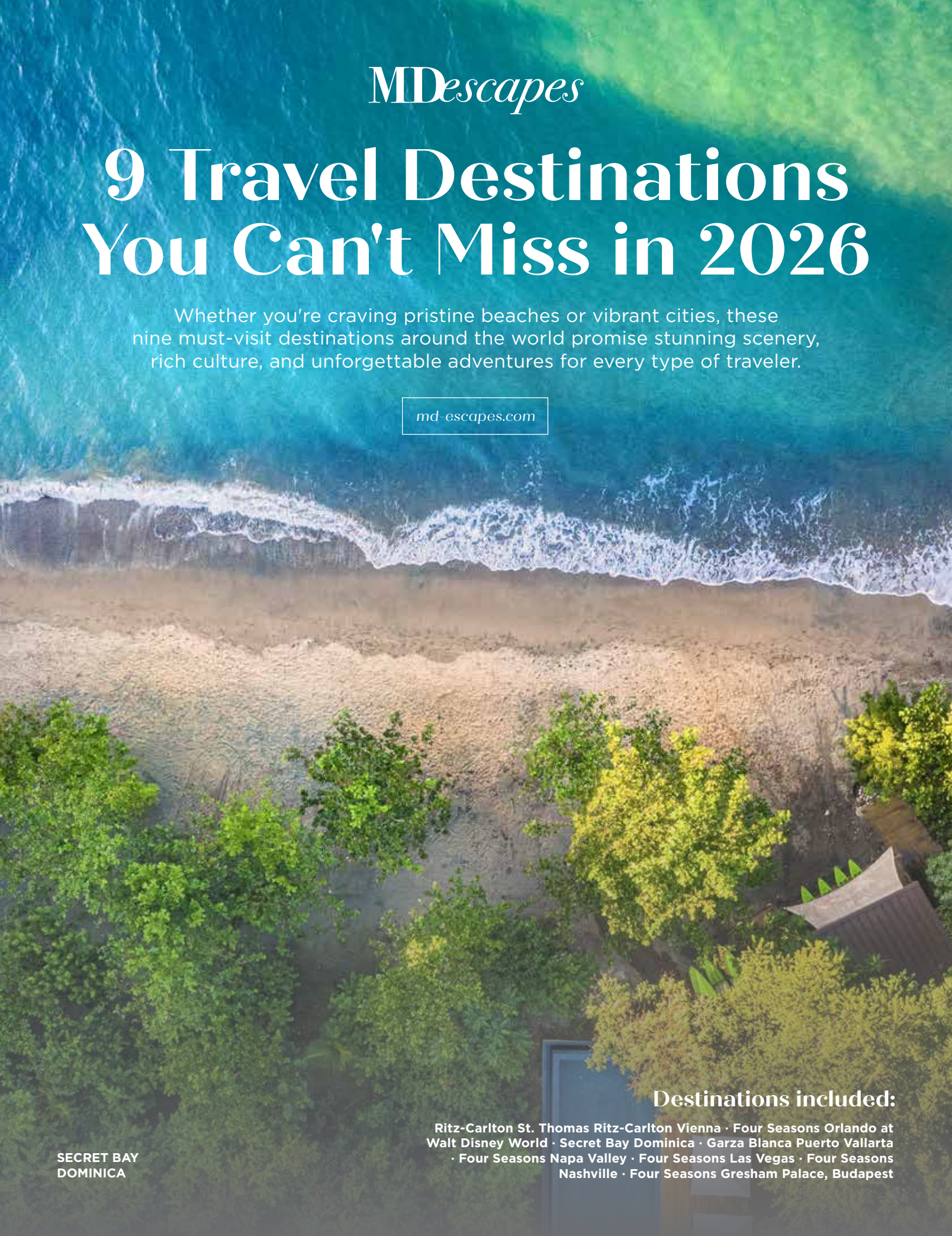
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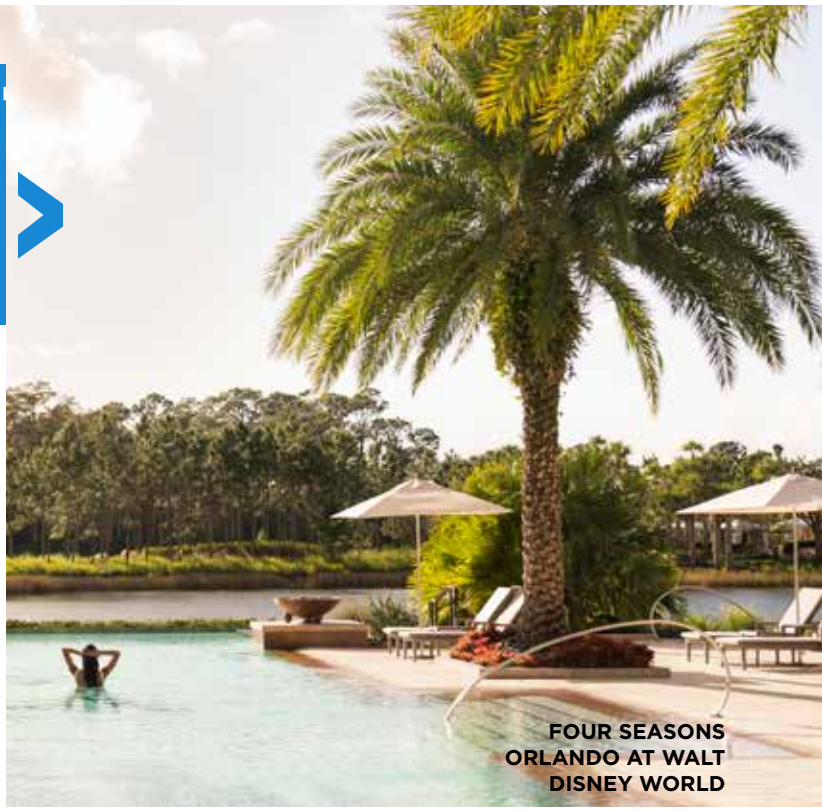
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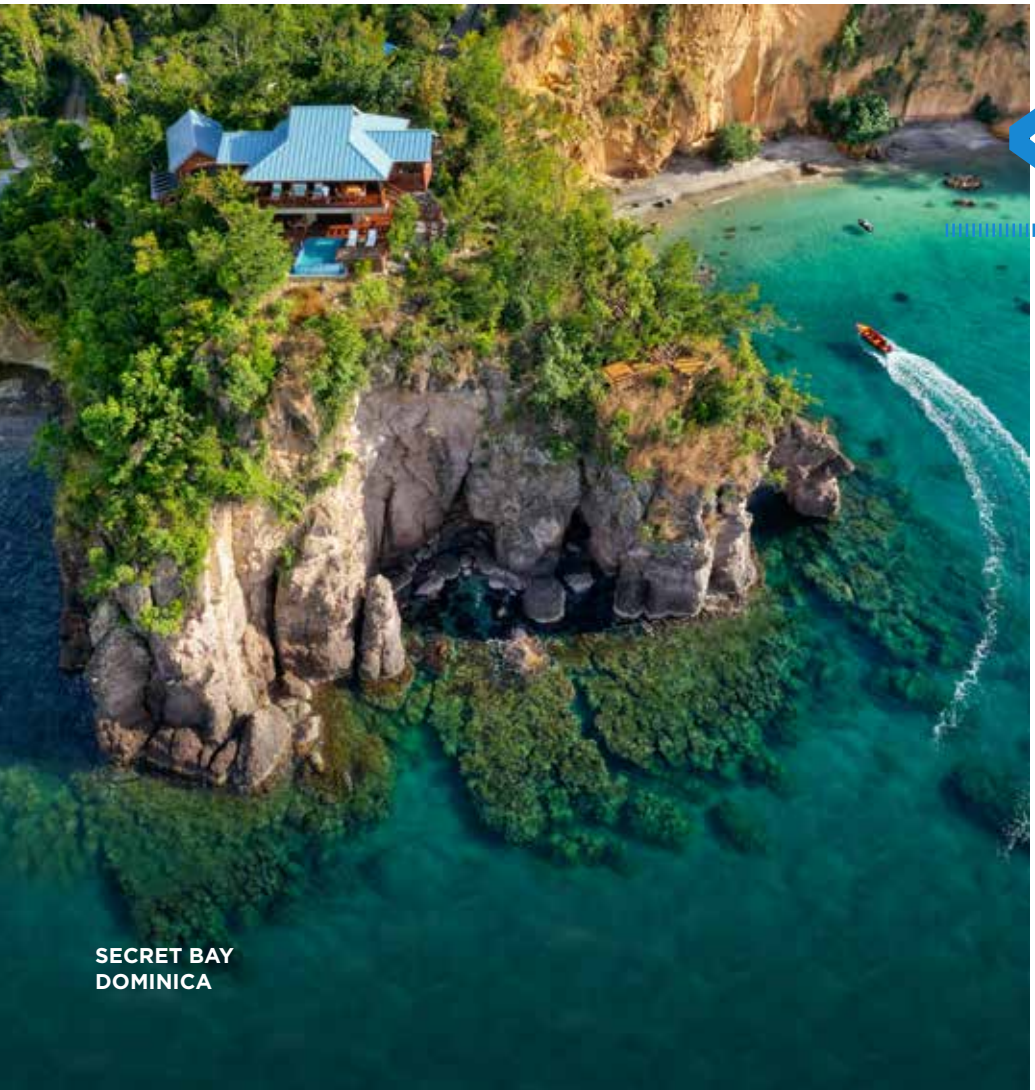
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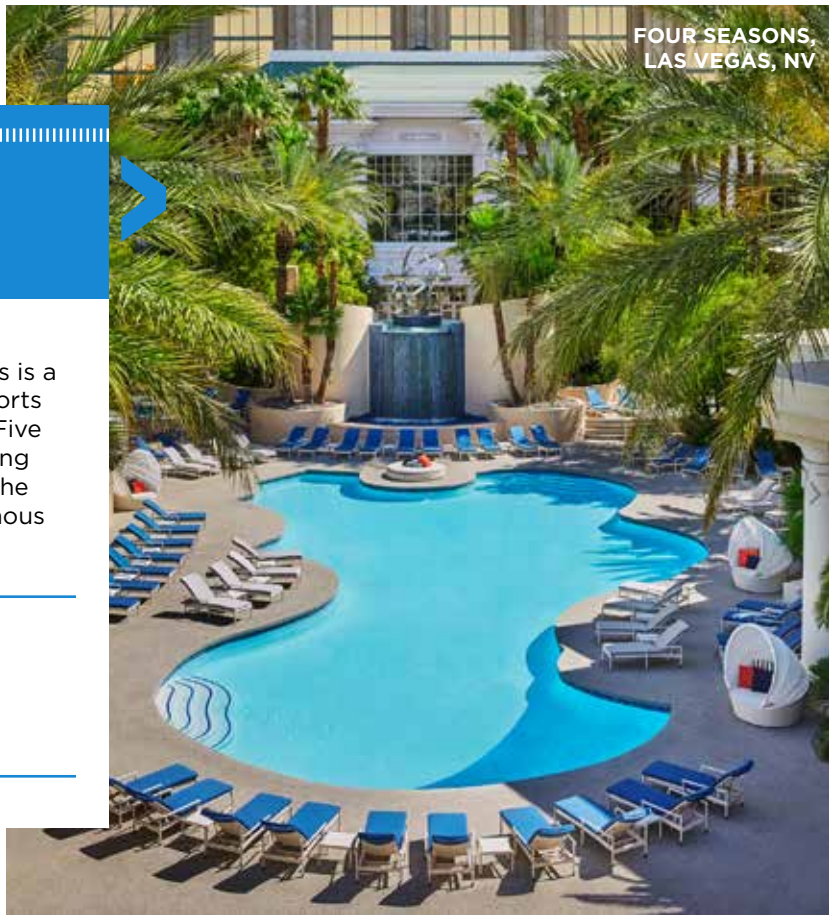

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