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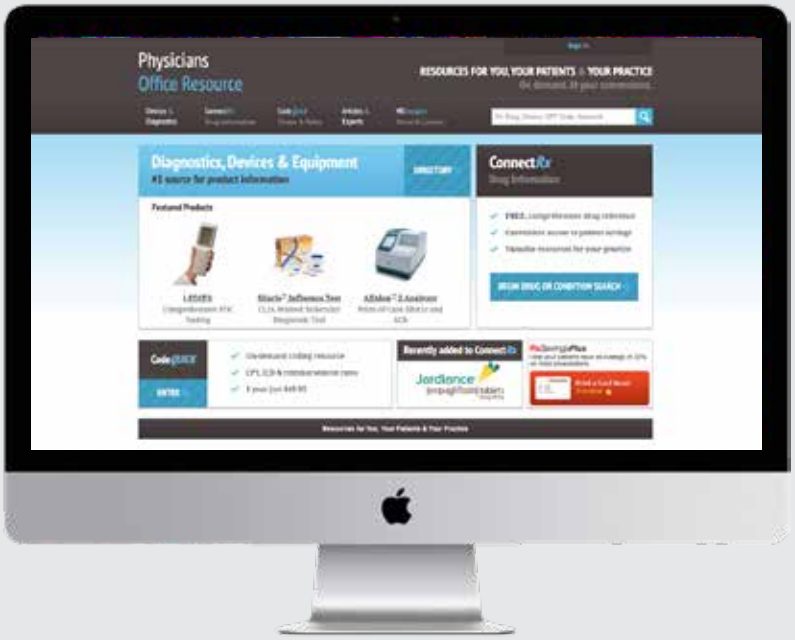
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PUBLISHED BY
Medical Education Resources, LLC

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DIAGNOSING AND TREATING RESPIRATORY INFECTIONS IN THE OUTPATIENT SETTING

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[1] Brown, H. *Improving the Diagnosis of Vulvovaginitis.* Population Health Management. Vol. 23, suppl 1, 2020

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FEATURE



Diagnosing and treating respiratory infections in the outpatient setting:

Antimicrobial use, infection prevention, and improved patient care.

BY ANDREA PRINZI PHD, MPH, SM(ASCP), MICROBIOLOGY MEDICAL SCIENCE LIAISON, US MEDICAL AFFAIRS AT BIOMÉRIEUX

The Threat of Antimicrobial Resistance

Antimicrobial resistance (AMR) occurs when microorganisms evolve and adapt, making treatment with antimicrobials (e.g., antibiotics, antiviral, and antifungal medications) ineffective. When this occurs, infections caused by drug-resistant organisms may become exceptionally difficult, or even impossible, to treat.[1] The World Health Organization (WHO) has declared AMR one of humanity's top 10 public health threats.[1] It is estimated that in 2019 alone, approximately 1.27 million deaths were directly attributable to infections caused by drug-resistant organisms globally.[2] In the United States, more than 2.8 million antibiotic-resistant infections are reported, and more than 35,000 people die due to AMR each year.[3] Simply relying on the development of new antimicrobials that are effective against drug-resistant organisms is no longer enough. According to the Centers for Disease Control and Prevention (CDC), drug development programs must be coupled with multiple initiatives to combat AMR and keep the public safe. These initiatives include preventing infections, slowing the development of AMR through initiatives encouraging more appropriate antibiotic use, and preventing the spread of antibiotic-resistant organisms when identified.[3]

Antibiotic Use in the Outpatient Setting

Inappropriate antibiotic use is a significant challenge in the outpatient setting (e.g., physician's offices, urgent care clinics). In the U.S., it is estimated that at least 30% of the antibiotics prescribed in the outpatient setting are unnecessary, meaning that an antibiotic is not needed for the patient to improve clinically.[4] Respiratory infections are a major driver of unnecessary and inappropriate antibiotic use in the outpatient setting. For example, rhinosinusitis (commonly referred to as a sinus infection and involving inflammation of the sinuses, nasal cavity, and nasal mucosa)[5] is one of the most commonly diagnosed respiratory conditions in the U.S. and is the fifth most common diagnosis associated with antibiotic therapy.[5] In adults, 90-98% of sinusitis cases are caused by a virus and should not be treated with antibiotics.[6] Additionally, other upper respiratory tract infections (most often referred to as "the common cold") also represent one of the major reasons for physician office visits.[7] There are at least 200 viruses that can cause the common cold, and most of the time, antibiotics are not needed.[6] Unfortunately, upper respiratory tract infections can last for a long time (a week or longer) which may be frustrating for adults and especially worrisome for parents of young children. However, unnecessary antibiotic use is not without complications. In addition to contributing to AMR, antibiotic use has been associated with adverse side effects, including rashes, dizziness, vomiting and diarrhea, and yeast infections.8 In more serious cases, antibiotic use has been associated with severe allergic reactions and infection with Clostridioides difficile (C. difficile), which can cause life-threatening diarrhea.8 In children, inappropriate antibiotic use for treating infections in the ear and sinuses is associated with 3 to 8 times the risk of developing a C. difficile infection.[9]

In addition to the clinical impact of unnecessary antibiotic prescribing for respiratory tract infections, the social and economic impacts can be severe. In adults, antibiotic treatment failure, additional prescriptions, repeat visits, and follow-up testing for acute sinusitis contribute to a health-

care expenditure exceeding $3 billion in the U.S. annually.[5] A study published in 2017 demonstrated that in pediatrics, inappropriate antibiotic use for three common infections (ear infections, pharyngitis, and sinus infections) led to excess healthcare costs totaling $53.7 million.[9] Furthermore, antibiotic use in cases of respiratory tract infections caused by viruses increased healthcare costs by approximately $20.7 million.[9]

The Role of Rapid Diagnostic Testing for Respiratory Illness in The Outpatient Setting

Preventing infections before they occur

As seen with the COVID-19 pandemic, prevention of the spread of disease is key. Seasonal surveillance, or the act of collecting data on the viruses in the community causing illness over a defined period of time, is important to identify expected trends but also to catch upticks in disease that may suggest an outbreak or epidemic. Historically, respiratory testing data collected from patient testing in the clinical laboratory have been sent to surveillance programs like the CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS). This system analyzes patterns across time and place of respiratory illnesses to monitor viral seasons and circulation patterns for various common respiratory viruses.[10] Data are submitted to the CDC from participating laboratories on a voluntary weekly basis. Although there are a variety of disease surveillance options available that are web-based, they still require manual entry of data from laboratories which can be time-consuming, associated with delays in reporting, or potentially prone to error.[11]

However, tracking respiratory data in real time is now an option. [11] BIOFIRE® Syndromic Trends (TREND), from bioMérieux, is a software program that collects data from respiratory testing performed on bioMérieux's BIOFIRE respiratory assays and provides insights into pathogen circulation trends.[12] The use of epidemiologic data tools like BIOFIRE TREND provides a high-resolution summary of circulating respiratory pathogens and could potentially aid in detecting new outbreaks by monitoring what is spreading within the community in near-real-time.[11] This is an important step in reducing the burden of respiratory disease and contributing to outbreak responses and vaccine development.[13] The opportunity to have data move directly from a multiplex PCR assay to an accessible cloud may remove the barrier of manual reporting typically performed by a clinical laboratory, making this an appealing option for use in the outpatient setting.

Supporting Appropriate Antimicrobial Use

Many behavioral complexities play into clinical decision-making and antibiotic prescribing practices. Pressure to prescribe an antibiotic, particularly pressure from the parents of pediatric patients, is cited as a major driver of unnecessary antibiotic use in the outpatient setting.[14] Furthermore, diagnostic uncertainty contributes to antibiotic overuse. The symptoms of viral and bacterial respiratory infections are often similar, and it can be difficult to differentiate between them. In the outpatient setting, where it may be challenging or less desirable to perform a procedure to test for this, a clinician may prescribe an antibiotic because it feels like a safer choice.[15] Knowing what is causing a patient's respiratory infection may support clinicians in their conversations with patients and may help patients (or parents of patients) feel more comfortable about not receiving an antibiotic.[15]

Time constraints are another significant challenge for clinicians in the outpatient setting. Studies that involved interviewing physicians about factors that contribute to antibiotic over-prescription found that workload and time pressures contribute to the problem. Physicians report that as they see more patients repeatedly throughout the day, they are subject to "decision fatigue."[15] Decision fatigue results in declining decision-making abilities after clinicians have to make repeated decisions. This may be more prevalent in the case of acute respiratory infection, where the cause of the disease is often unknown and prescribing an antibiotic feels safe.[15]

Until recently, the primary respiratory tests available to outpatient doctor's offices were rapid antigen detection tests (RADTs). Although relatively cheap and easy to use, RADTs are limited by poor performance, including low sensitivity (the ability of a test to detect a pathogen when it is present) and marginal specificity (the ability of a test to give a negative result when a pathogen is not present). Additionally, the performance of RADTs varies depending on what time of year they are used. For example, when the prevalence of influenza is low within a community, false positive results from an antigen test are more likely. However, negative results are more likely to be true.[16]

Rapid point-of-care multiplex PCR assays are now available in the outpatient setting. These tests are faster, more comprehensive, and perform better than traditional RADTs.[17] For example, the bioMérieux BIOFIRE® SPOTFIRE® Respiratory (R) Panel assay tests for 15 respiratory pathogens and offers a result in about 15 minutes. Paired with education about how antibiotics will not help patients with viral infections, excessive antibiotic use may be reduced by the use of molecular multiplex PCR assays. The Infectious Diseases Society of America (IDSA) states that multiplex PCR testing is indicated when detecting a respiratory virus would influence the decision to withhold unnecessary antibiotics.[18] In addition to potentially preventing the overuse of unnecessary therapy, the knowledge gained from respiratory multiplex PCR testing has been shown to support appropriate antiviral therapy, like those used to treat influenza.[19] The rapid turnaround time for results from a multiplex PCR assay may help support workflow and clinical decision-making in busy outpatient settings and support more effective patient management and care. In a 2020 publication discussing the role of PCR testing for respiratory tract infections, the IDSA stated that respiratory test results (e.g., influenza) must be available

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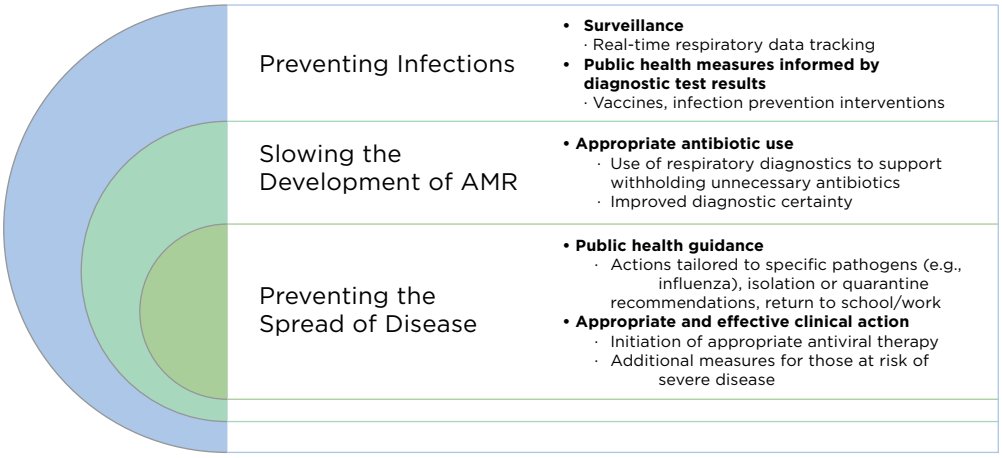
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Figure 1. The Role of Respiratory Diagnostics in Supporting AMR Initiatives



during the patient visit to be useful in the outpatient setting.[18] Given this, rapid diagnostic assays for respiratory illness that offer test results quickly (e.g., about 15 minutes) have the potential to provide meaningful clinical results while the patient is still in the office.

Preventing the Spread of Future Infections

The COVID-19 pandemic demonstrated, in real-time, the importance of diagnostic testing and its impact on public health interventions and how people live their lives. The far-reaching effects of the pandemic not only touched individuals' physical health but also led to significant societal disruption and economic loss.[20] Knowledge is power, and accurate diagnostic testing in the outpatient setting may help inform public health actions like social distancing or masking on an individual and population health level.[21] The impact of diagnostic testing on preventing severe disease, hospitalization, and spread is well-demonstrated for influenza. For example, it is estimated that influenza has led to 12,000-52,000 deaths annually between 2010 and 2020 in the U.S. If the diagnosis of influenza is early enough, antiviral drugs can be prescribed, which can shorten the length of illness and make symptoms of the disease milder.[22] Additionally, the CDC recommends that individuals with known influenza stay home for at least 24 hours after their fever is gone to help prevent the spread of the disease.[22] Obtaining information about the causative agent of respiratory disease, paired with appropriate preventative measures, may help protect the most vulnerable individuals in a population.

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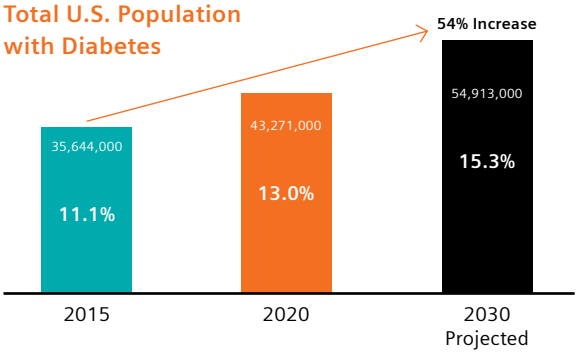


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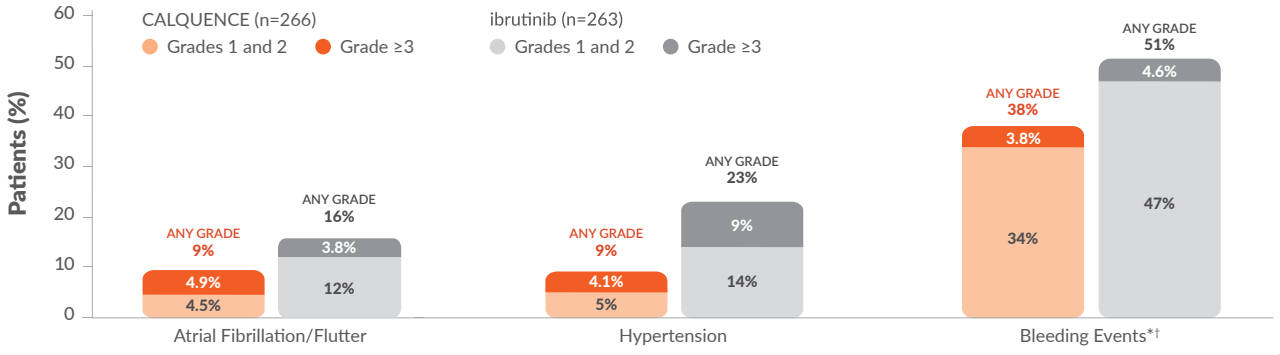
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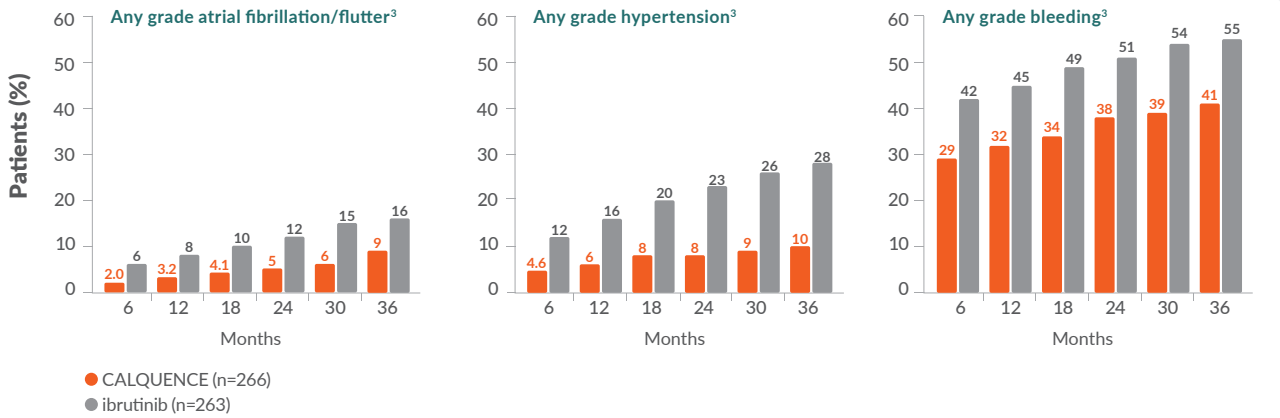
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Post hoc analysis of cumulative incidence‡ of select AEs of clinical interest[3]



The ELEVATE-RR data have not been reviewed by the FDA and are not included in the prescribing information for CALQUENCE.

*Includes major bleeding events, which were defined as any hemorrhagic event that was serious, Grade ≥3 in severity, or that was a central nervous system hemorrhage (any grade), occurred in 4.5% of CALQUENCE patients and 5% of ibrutinib patients.[1]
†Bleeding events occurring in ≥10% of patients in either treatment arm include contusion and epistaxis.[1,3]
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Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

CALQUENCE®
acalabrutinib 100 mg tablets



ELEVATE-RR: CALQUENCE VS IBRUTINIB

The first head-to-head study of a BTKi vs ibrutinib in R/R CLL[1]

ELEVATE-RR was a Phase 3, open-label, randomized, multicenter trial in 533 patients with relapsed/refractory CLL and the presence of 17p deletion and/or 11q deletion. Patients received either CALQUENCE 100 mg orally approximately every 12 hours (n=268) or ibrutinib 420 mg orally once daily (n=265) until disease progression or unacceptable toxicity. The primary endpoint was IRC-assessed PFS (non-inferiority*; tested after ~250 events). Secondary endpoints included incidence of any grade atrial fibrillation, incidence of Grade ≥3 infections, incidence of Richter's transformation, and OS.[1]

Safety and tolerability data at 40.9-month median follow-up[1]

Most common AEs (>15%, any grade) in ELEVATE-RR[1]

	CALQUENCE (n=266)		ibrutinib (n=263)	
Adverse event	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Headache	35	1.5	20	0
Diarrhea	35	1.1	46	4.9
Cough	29	0.8	21	0.4
Upper respiratory tract infection	27	1.9	25	0.4
Pyrexia	23	3.0	19	0.8
Anemia	22	12	19	13
Neutropenia	21	20	25	23
Fatigue	20	3.4	17	0
Pneumonia	18	11	16	9
Nausea	18	0	19	0.4
Arthralgia	16	0	23	0.8
Thrombocytopenia	15	10	13	7
Contusion	12	0	18	0.4
Atrial fibrillation	9†	4.5	16†	3.4
Hypertension	9	4.1	23	9

- Adverse events of clinical interest (any grade) in patients receiving CALQUENCE included infections (78%), cytopenias (41%), bleeding events (38%), cardiac events (24%), and second primary malignancies, excluding non-melanoma skin cancers (9%)[1]
- The median duration of CALQUENCE exposure was 38.3 months (range: 0.3-55.9); the median duration of ibrutinib exposure was 35.5 months (range: 0.2-57.7)[1]

*Derivation of the non-inferiority margin (upper bound of HR two-sided 95% CI <1.429) was based on the results of one ibrutinib study. Therefore, it may be difficult to verify the constancy assumption of the historical control.[1]
†Select secondary endpoint.[1]

AEs=adverse events; BR=bendamustine + rituximab; BTKi=Bruton tyrosine kinase inhibitor; CI=confidence interval; CLL=chronic lymphocytic leukemia; HR=hazard ratio; IdR=idelalisib + rituximab; INV=investigator; IRC=Independent Review Committee; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; R/R=relapsed/refractory.

ASCEND: RELAPSED/REFRACTORY CLL

The first study of a BTKi vs IdR or BR in R/R CLL[2,4]

ASCEND was a Phase 3, open-label, randomized, multicenter trial in 310 patients with relapsed/refractory CLL. Patients received either CALQUENCE monotherapy 100 mg approximately every 12 hours until disease progression or unacceptable toxicity (n=155) or investigator's choice of IdR or BR (n=155). Primary endpoint at the interim analysis (median follow-up of 16.1 months) was IRC-assessed PFS. After the interim analysis at 16.1-month median follow-up, PFS was INV-assessed only. Select secondary endpoints were ORR, OS, and safety.[2,4]

Safety and tolerability data at 46.5-month median follow-up[2]

Most common AEs (>15%, any grade) in ASCEND[2]

	CALQUENCE (n=154)		IdR (n=118)		BR (n=35)	
Adverse event	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Infection	68	29	73	34	49	11
Upper respiratory tract infection	20	1.9	17	3.4	11	2.9
Pneumonia	19	10	14	10	6	2.9
Hemorrhage	31	2.6	8	2.5	6	2.9
Major hemorrhage*	3.2	2.6	2.5	2.5	2.9	2.9
Neutropenia	24	19	47	40	34	31
Headache	23	0.6	6	0	0	0
Diarrhea	21	1.9	53	26	14	0
Anemia	18	13	11	7	11	9
Cough	18	0	15	0.8	6	0
Pyrexia	16	3.2	19	7	17	2.9

- The median duration of CALQUENCE exposure was 44.2 months (range: 1.1-54.2)[2]

- **At 16.1-month median follow-up**, the most common adverse reactions (≥20%) of any grade in patients receiving CALQUENCE were infection (56%), neutropenia (48%), anemia (47%), thrombocytopenia (33%), lymphocytosis (26%), and headache (22%)[4]
  - Events of clinical interest (any grade; Grade ≥3) included infection (56%; 15%), bleeding (26%; 1.9%), atrial fibrillation (5%; 1.3%), and hypertension (3.2%; 1.9%)[4,5]
  - The median duration of CALQUENCE exposure was 15.7 months (range: 1.1-22.4)[4,5]

The median 46.5-month follow-up data from ASCEND have not been reviewed by the FDA and are not included in the Prescribing Information for CALQUENCE.

*Major hemorrhage was defined as any serious or Grade ≥3 hemorrhage or central nervous system hemorrhage of any grade, excluding immune thrombocytopenic purpura.[2]

VIEW HEAD-TO-HEAD TRIAL RESULTS AT CALQUENCEHCP.COM

SELECT SAFETY INFORMATION (cont'd)

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

Please see Brief Summary of full Prescribing Information on adjacent pages.

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. Byrd JC, Hillmen P, Ghia P, et al. Acalabrutinib versus ibrutinib in previously treated chronic lymphocytic leukemia: results of the first randomized phase III trial. *J Clin Oncol.* 2021;39(31):3441-3452 and supplementary appendix. **2.** Ghia P, Pluta A, Wach M, et al. Acalabrutinib versus investigator's choice in relapsed/refractory chronic lymphocytic leukemia: final ASCEND trial results. *Hemasphere.* 2022;6(12):e801. **3.** Seymour JF, Byrd JC, Hillmen P, et al. Characterization of Bruton tyrosine kinase inhibitor (BTKi)-related adverse events in a head-to-head trial of acalabrutinib versus ibrutinib in previously treated chronic lymphocytic leukemia (CLL). Poster presented at the American Society of Hematology (ASH) Annual Meeting; December 11-14, 2021. Abs 3721. **4.** CALQUENCE® (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022. **5.** Ghia P, Pluta A, Wach M, et al. ASCEND: phase III, randomized trial of acalabrutinib versus idelalisib plus rituximab or bendamustine plus rituximab in relapsed or refractory chronic lymphocytic leukemia. *J Clin Oncol.* 2020;38(25):2849-2861 and supplementary appendix.

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AstraZeneca

CALQUENCE® (acalabrutinib) tablets, for oral use
Initial U.S. Approval: 2017

Brief Summary of Prescribing Information.
For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
CALQUENCE is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

DOSAGE AND ADMINISTRATION

Recommended Dosage

CALQUENCE as Monotherapy
For patients with CLL, or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

CALQUENCE in Combination with Obinutuzumab
For patients with previously untreated CLL or SLL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity. Start CALQUENCE at Cycle 1 (each cycle is 28 days). Start obinutuzumab at Cycle 2 for a total of 6 cycles and refer to the obinutuzumab prescribing information for recommended dosing. Administer CALQUENCE prior to obinutuzumab when given on the same day.

Advise patients to swallow tablet whole with water. Advise patients not to chew, crush, dissolve, or cut the tablets. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra tablets of CALQUENCE should not be taken to make up for a missed dose.

Recommended Dosage for Drug Interactions

Dosage Modifications for Use with CYP3A Inhibitors or Inducers
These are described in Table 1 *[see Drug Interactions (7) in the full Prescribing Information]*.

Table 1: Recommended Dosage Modifications for Use with CYP3A Inhibitors or Inducers

CYP3A	Co-administered Drug	Recommended CALQUENCE use
Inhibition	Strong CYP3A inhibitor	Avoid co-administration. If these inhibitors will be used short-term (such as anti-infectives for up to seven days), interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.
	Moderate CYP3A inhibitor	Reduce the CALQUENCE 100 mg every 12 hours dosage to 100 mg once daily.
Induction	Strong CYP3A inducer	Avoid co-administration. If co-administration is unavoidable, increase CALQUENCE dosage to 200 mg approximately every 12 hours.

Dosage Modifications for Adverse Reactions
Recommended dosage modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications for Adverse Reactions

Event	Adverse Reaction Occurrence	Dosage Modification (Starting dose = 100 mg approximately every 12 hours)
Grade 3 or greater non-hematologic toxicities, Grade 3 thrombocytopenia with bleeding, Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days	First and Second	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at 100 mg approximately every 12 hours.
	Third	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at a reduced frequency of 100 mg once daily.
	Fourth	Discontinue CALQUENCE.

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE).

Refer to the obinutuzumab prescribing information for management of obinutuzumab toxicities.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Serious and Opportunistic Infections
Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%) *[see Adverse Reactions (6.1) in the full Prescribing Information]*. These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage
Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias
Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dosage and Administration (2.3) in the full Prescribing Information]*.

Second Primary Malignancies
Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials *[see Adverse Reactions (6.1) in the full Prescribing Information]*. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter
Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (e.g., palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious and Opportunistic Infections *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hemorrhage *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Cytopenias *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Atrial Fibrillation and Flutter *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

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

The data in the Warnings and Precautions reflect exposure to CALQUENCE 100 mg approximately every 12 hours in 1029 patients with hematologic malignancies. Treatment includes CALQUENCE monotherapy in 820 patients in 6 trials, and CALQUENCE with obinutuzumab in 209 patients in 2 trials. Among these recipients of CALQUENCE, 88% were exposed for at least 6 months and 79% were exposed for at least one year. In this pooled safety population, adverse reactions in ≥ 30% of 1029 patients were anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain.

Chronic Lymphocytic Leukemia
The safety data described below reflect exposure to CALQUENCE (100 mg approximately every 12 hours, with or without obinutuzumab) in 511 patients with CLL from two randomized controlled clinical trials *[see Clinical Studies (14.2) in the full Prescribing Information]*.

The most common adverse reactions (≥ 30%) of any grade in patients with CLL were anemia, neutropenia, thrombocytopenia, headache, upper respiratory tract infection, and diarrhea.

ELEVATE-TN
The safety of CALQUENCE plus obinutuzumab (CALQUENCE+G), CALQUENCE monotherapy, and obinutuzumab plus chlorambucil (GClb) was evaluated in a randomized, multicenter, open-label, actively controlled trial in 526 patients with previously untreated CLL *[see Clinical Studies (14.2) in the full Prescribing Information]*.

Patients randomized to the CALQUENCE+G arm were treated with CALQUENCE and obinutuzumab in combination for six cycles, then with CALQUENCE as monotherapy until disease progression or unacceptable toxicity. Patients initiated obinutuzumab on Day 1 of Cycle 2, continuing for a total of 6 cycles. Patient randomized to CALQUENCE monotherapy received CALQUENCE approximately every 12 hours until disease progression or unacceptable toxicity. The trial required age ≥ 65 years of age or 18 to < 65 years of age with a total Cumulative Illness Rating Scale (CIRS) > 6 or creatinine clearance of 30 to 69 mL/min, hepatic transaminases ≤ 3 times ULN and total bilirubin ≤1.5 times ULN, and allowed patients to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonists.

During randomized treatment, the median duration of exposure to CALQUENCE in the CALQUENCE+G and CALQUENCE monotherapy arms was 27.7 months (range 0.3 to 40 months), with 95% and 92% and 89% and 86% of patients with at least 6 months and 12 months of exposure, respectively. In the obinutuzumab and chlorambucil arm, the median number of cycles was 6 with 84% of patients receiving at least 6 cycles of obinutuzumab, 70% of patients received at least 6 cycles of chlorambucil. Eighty-five percent of patients in the CALQUENCE+G arm received at least 6 cycles of obinutuzumab.

In the CALQUENCE+G and CALQUENCE monotherapy arms, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE+G arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (2.8% to 7%).

In the CALQUENCE+G arm, adverse reactions led to treatment discontinuation in 11% of patients and a dose reduction of CALQUENCE in 7% of patients. In the CALQUENCE monotherapy arm, adverse reactions led to discontinuation in 10% and dose reduction in 4% of patients.

Tables 5 and 6 present adverse reactions and laboratory abnormalities identified in the ELEVATE-TN trial.

Table 5: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ELEVATE-TN)

Body System Adverse Reaction*	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection†	69	22‡	65	14‡	46	13‡
Upper respiratory tract infection§	39	2.8	35	0	17	1.2
Lower respiratory tract infection¶	24	8	18	4.5	7	1.8
Urinary tract infection	15	1.7	15	2.8	5	0.6
Blood and lymphatic system disorders#						
Neutropenia€	53	37	23	13	78	50
Anemia£	52	12	53	10	54	14
Thrombocytopenia¥	51	12	32	3.4	61	16
Lymphocytosis¶	12	11	16	15	0.6	0.6
Nervous system disorders						
Headache	40	1.1	39	1.1	12	0
Dizziness	20	0	12	0	7	0
Gastrointestinal disorders						
Diarrhea	39	4.5	35	0.6	21	1.8
Nausea	20	0	22	0	31	0
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain¶	37	2.2	32	1.1	16	2.4
Arthralgia	22	1.1	16	0.6	4.7	1.2
General disorders and administration site conditions						
Fatigue¶	34	2.2	23	1.1	24	1.2
Skin and subcutaneous tissue disorders						
Bruising¶	31	0	21	0	5	0
Rash¶	26	2.2	25	0.6	9	0.6
Vascular disorders						
Hemorrhage¶	20	1.7	20	1.7	6	0

* Per NCI CTCAE version 4.03
† Includes any adverse reactions involving infection or febrile neutropenia
‡ Includes 3 fatal cases in the CALQUENCE plus obinutuzumab arm, 3 fatal cases in the CALQUENCE monotherapy arm and 1 fatal case in the obinutuzumab plus chlorambucil arm

§ Includes upper respiratory tract infection, nasopharyngitis and sinusitis
[a] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection
[b] Derived from adverse reaction and laboratory data
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell count decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased, and related laboratory data
[g] Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity and spinal pain
[h] Includes asthenia, fatigue, and lethargy
[i] Includes bruise, contusion, and ecchymosis
[j] Includes rash, dermatitis, and other related terms
[k] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE (CALQUENCE in combination with obinutuzumab and monotherapy) included:

- *Neoplasms:* second primary malignancy (10%), non-melanoma skin cancer (5%)
- *Cardiac disorders:* atrial fibrillation or flutter (3.6%), hypertension (5%)
- *Infection:* herpesvirus infection (6%)

Table 6: Select Non-Hematologic Laboratory Abnormalities (≥ 15% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ELEVATE-TN)

Laboratory Abnormality*, [a]	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	29	29	22	22	37	37
ALT increase	30	7	20	1.1	36	6
AST increase	38	5	17	0.6	60	8
Bilirubin increase	13	0.6	15	0.6	11	0.6

*Per NCI CTCAE version 4.03
[a] Excludes electrolytes

Increases in creatinine to 1.5 to 3 times ULN occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

ASCEND

The safety of CALQUENCE in patients with relapsed or refractory CLL was evaluated in a randomized, open-label study (ASCEND) *[see Clinical Studies (14.2) in the full Prescribing Information]*. The trial enrolled patients with relapsed or refractory CLL after at least one prior therapy and required hepatic transaminases ≤ 2 times ULN, total bilirubin ≤ 1.5 times ULN, and an estimated creatinine clearance ≥ 30 mL/min. The trial excluded patients having an absolute neutrophil count < 500/µL, platelet count < 30,000/µL, prothrombin time or activated partial thromboplastin time > 2 times ULN, significant cardiovascular disease, or a requirement for strong CYP3A inhibitors or inducers. Patients were allowed to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonist.

In ASCEND, 154 patients received CALQUENCE (100 mg approximately every 12 hours until disease progression or unacceptable toxicity), 118 received idelalisib (150 mg approximately every 12 hours until disease progression or unacceptable toxicity) with up to 8 infusions of a rituximab product, and 35 received up to 6 cycles of bendamustine and a rituximab product. The median age overall was 68 years (range: 32-90); 67% were male; 92% were white; and 88% had an ECOG performance status of 0 or 1.

In the CALQUENCE arm, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in > 5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

In recipients of CALQUENCE, permanent discontinuation due to an adverse reaction occurred in 10% of patients, most frequently due to second primary malignancies followed by infection. Adverse reactions led to dosage interruptions of CALQUENCE in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and dose reduction in 3.9% of patients.

Selected adverse reactions are described in Table 7 and non-hematologic laboratory abnormalities are described in Table 8. These tables reflect exposure to CALQUENCE with median duration of 15.7 months with 94% of patients on treatment for greater than 6 months and 86% of patients on treatment for greater than 12 months. The median duration of exposure to idelalisib was 11.5 months with 72% of patients on treatment for greater than 6 months and 48% of patients on treatment for greater than 12 months. Eighty-three percent of patients completed 6 cycles of bendamustine and rituximab product.

Table 7: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ASCEND)

Body System Adverse Reaction*	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection†	56	15‡	65	28‡	49	11
Upper respiratory tract infection§	29	1.9	26	3.4	17	2.9
Lower respiratory tract infection[a]	23	6	26	15	14	6
Blood and lymphatic system disorders[b]						
Neutropenia[c]	48	23	79	53	80	40
Anemia[d]	47	15	45	8	57	17
Thrombocytopenia[e]	33	6	41	13	54	6
Lymphocytosis[f]	26	19	23	18	2.9	2.9
Nervous system disorders						
Headache	22	0.6	6	0	0	0
Gastrointestinal disorders						
Diarrhea[g]	18	1.3	49	25	14	0
Vascular disorders						
Hemorrhage[h]	16	1.3	5	1.7	6	2.9
General disorders						
Fatigue[i]	15	1.9	13	0.8	31	6
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain[j]	15	1.3	15	1.7	2.9	0

* Per NCI CTCAE version 4.03
† Includes any adverse reactions involving infection or febrile neutropenia
‡ Includes 1 fatal case in the CALQUENCE monotherapy arm and 1 fatal case in the Idelalisib plus Rituximab arm
§ Includes upper respiratory tract infection, rhinitis and nasopharyngitis
[a] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection
[b] Derived from adverse reaction and laboratory data
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased and related laboratory data
[g] Includes colitis, diarrhea, and enterocolitis
[h] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis
[i] Includes asthenia, fatigue, and lethargy
[j] Includes back pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, pain in extremity, myalgia, spinal pain and bone pain

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE included:

- *Skin and subcutaneous disorders:* bruising (10%), rash (9%)
- *Neoplasms:* second primary malignancy (12%), non-melanoma skin cancer (6%)
- *Musculoskeletal and connective tissue disorders:* arthralgia (8%)
- *Cardiac disorders:* atrial fibrillation or flutter (5%), hypertension (3.2%)
- *Infection:* herpesvirus infection (4.5%)

Table 8: Select Non-Hematologic Laboratory Abnormalities (≥ 10% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ASCEND)

Laboratory Abnormality [a]	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	15	15	11	11	23	23
ALT increase	15	1.9	59	23	26	2.9
AST increase	13	0.6	48	13	31	2.9
Bilirubin increase	13	1.3	16	1.7	26	11

Per NCI CTCAE version 5
[a] Excludes electrolytes

Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to animals during organogenesis resulted in dystocia in rats and reduced fetal growth in rabbits at maternal exposures (AUC) 2 times exposures in patients at the recommended dose of 100 mg approximately every 12 hours (*see Data*). Advise pregnant women of the potential risk to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background 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 to 4% and 15 to 20%, respectively.

Data

Animal Data

In a combined fertility and embryo-fetal development study in female rats, acalabrutinib was administered orally at doses up to 200 mg/kg/day starting 14 days prior to mating through gestational day [GD] 17. No effects on embryo-fetal development and survival were observed. The AUC at 200 mg/kg/day in pregnant rats was approximately 9 times the AUC in patients at the recommended dose of 100 mg approximately every 12 hours. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rabbits, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours.

In a pre- and postnatal development study in rats, acalabrutinib was administered orally to pregnant animals during organogenesis, parturition and lactation, at doses of 50, 100, and 150 mg/kg/day. Dystocia (prolonged or difficult labor) and mortality of offspring were observed at doses ≥ 100 mg/kg/day. The AUC at 100 mg/kg/day in pregnant rats was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours. Underdeveloped renal papilla was also observed in F1 generation offspring at 150 mg/kg/day with an AUC approximately 5 times the AUC in patients at 100 mg approximately every 12 hours.

Lactation

Risk Summary

No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from CALQUENCE, advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

CALQUENCE may cause embryo-fetal harm and dystocia when administered to pregnant women *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Pediatric Use

The safety and efficacy of CALQUENCE in pediatric patients have not been established.

Geriatric Use

Of the 929 patients with CLL or MCL in clinical trials of CALQUENCE, 68% were 65 years of age or older, and 24% were 75 years of age or older. Among patients 65 years of age or older, 59% had Grade 3 or higher adverse reactions and 39% had serious adverse reactions. Among patients younger than age 65, 45% had Grade 3 or higher adverse reactions and 25% had serious adverse reactions. No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

Hepatic Impairment

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. The safety of CALQUENCE has not been evaluated in patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Distributed by:
AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

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08/22 US-66174 8/22



2724

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From Abbott

The CELL-DYN Emerald 22 is a full performance 5-part hematology analyzer for smaller clinical laboratories seeking productivity in smaller spaces.

Benefits:
• Compact Design - To conserve valuable workspace.
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• Ease Of Use
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2725





2726

MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITEDM

From HORIBA Medical

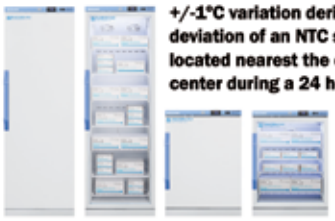
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Solid & Glass Door Refrigerators From 1 to 15 Cu.ft.



+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the chamber geometric center during a 24 hour test period

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Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	$936.00
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	$949.00
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	$1,089.00
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	$1,102.00
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	$1,235.00
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	$1,266.00
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	$1,654.00
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	$1,667.00
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	$2,139.00
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	$2,152.00
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	$2,321.00
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	$2,334.00

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$2,789.00
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	$3,114.00
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$4,674.00
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	$5,031.00

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$3,205.00
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$5,194.00

Choosing the Right Sized Unit

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

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

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

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) **x 1.25**

Maximum doses = _____

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

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

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privigen®
Immune Globulin Intravenous (Human), 10% Liquid

PROVEN EFFECTIVE IN PATH, the largest CIDP clinical trial*

Improves functional **ability**

Featuring proline for Ig **stability**



Important Safety Information

Privigen is indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  - Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

See full prescribing information for complete boxed warning.

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine.

Hyperproteinemia, increased serum viscosity, or hyponatremia can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral

PI & ITP SINCE **2007**

>1 MILLION PATIENT-YEARS OF THERAPY[1]

CIDP SINCE **2017**

Proven efficacy:

Overall response rates to Privigen were 61% and 73% in PRIMA and PATH,* respectively†

Rapid response:

Almost all who responded† to Privigen did so after 1–2 maintenance treatments at Weeks 4 and 7*

Demonstrated tolerability:

In both studies*, 97% of adverse reactions were mild or moderate in intensity with 2 and 8 subjects experiencing serious adverse reactions in PRIMA and PATH, respectively‡

Information for you and your patients:

Clinical information, patient resources, and videos at ConnectRx.com

Reference: 1. Data on file. Available from CSL Behring as PVG-006.

*In a prospective, open-label, single-arm, multicenter clinical study (Privigen Impact on Mobility and Autonomy [PRIMA]), 28 subjects with CIDP received a Privigen loading dose of 2 g/kg followed by Privigen maintenance doses of 1 g/kg every 3 weeks for up to 21 weeks with 3-week follow-up. In a second prospective, open-label Privigen prerandomization phase of a multicenter clinical study (Polyneuropathy and Treatment with Hizentra [PATH]), 207 IVIg-pretreated subjects with CIDP received a Privigen loading dose of 2 g/kg followed by up to 4 Privigen maintenance doses of 1 g/kg every 3 weeks for up to 13 weeks.

†Overall response rate was defined as percentage of subjects who experienced at least a 1-point decrease in adjusted INCAT score.

‡Serious adverse reactions included hemolysis (2), exacerbation of CIDP (2), acute rash, diastolic increased blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine. A total of 4 patients discontinued treatment due to serious adverse reactions.

Visit the Privigen page at ConnectRx.com for more information and to access support resources

anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common adverse reactions observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient's response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65, do not exceed recommended dose and infuse at the minimum rate practicable.

Please see the following brief summary of prescribing information for Privigen, including boxed warning.

Biotherapies for Life®

CSL Behring

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PRIVIGEN safely and effectively. See full prescribing information for PRIVIGEN.
PRIVIGEN® Immune Globulin Intravenous (Human), 10% Liquid
Initial U.S. Approval: 2007

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including PRIVIGEN. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PRIVIGEN does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or failure, administer PRIVIGEN at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

----------INDICATIONS AND USAGE----------

PRIVIGEN is an Immune Globulin Intravenous (Human), 10% Liquid indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

Limitations of Use:
PRIVIGEN maintenance therapy in CIDP has not been studied beyond 6 months.

----------CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reaction to human immune globulin
- Hyperprolinemia (PRIVIGEN contains the stabilizer L-proline)
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity

----------WARNINGS AND PRECAUTIONS----------

- IgA-deficient patients with antibodies to IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions.
- Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.
- Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion.
- Hemolysis that is either intravascular or due to enhanced red blood cell sequestration may occur. Risk factors include high doses and non-O blood group. Closely monitor patients for hemolysis and hemolytic anemia.
- Elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed during/shortly following PRIVIGEN infusion. These blood pressure elevations were resolved or significantly improved within hours with either observation alone or changes in oral anti-hypertensive therapy. Check patients for a history of hypertension and monitor blood pressure during and following PRIVIGEN infusion.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Carefully consider the relative risks and benefits before prescribing the high dose regimen (for chronic ITP and CIDP) in patients at increased risk of thrombosis, hemolysis, acute kidney injury, or volume overload.
- PRIVIGEN is made from human blood and may contain infectious agents, e.g., viruses, the variant Creutzfeldt Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

----------ADVERSE REACTIONS----------

- **PI** – The most common adverse reactions, observed in >5% of study subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.
- **Chronic ITP** – The most common adverse reactions, observed in >5% of study subjects, were laboratory findings consistent with hemolysis (hemoglobin and hematocrit decrease without blood loss in conjunction with positive direct antiglobulin test (DAT) and elevated blood lactate dehydrogenase (LDH) and/or indirect bilirubin), headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis.
- **CIDP –** The most common adverse reactions observed in >5% of study subjects were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, blood pressure diastolic increased, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may:

- Lead to misinterpretation of the results of serological testing.
- Interfere with the response to live virus vaccines.

----------USE IN SPECIFIC POPULATIONS----------

- Geriatric: In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse PRIVIGEN at the minimum rate practicable.

See 17 for PATIENT COUNSELING INFORMATION.

Based on March 2022 revision

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2728

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*The LumiraDx SARS-CoV-2 Ag test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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. S-COM-ART-02381 R3 2022/11



OSOM® BVBLUE®

From Sekisui Diagnostics

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

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OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

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

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ULTRA HCG COMBO TEST

From Sekisui Diagnostics

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

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3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing

2732

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

2 ANS Testing

(can be combined with SUDOMOTOR into 1 full system)

2733

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



3 SudoMotor Testing

2734

(can be combined with ANS into 1 full system)

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

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LEGITIMATE QUESTION:

is it possible to find trustworthy financial advice?!

Reasons to connect beyond your cousin's college roommate-turned-financial planner about your financial future

BY SCRUBMONEY™



It seems you can turn anywhere these days and you'll get financial advice. Look in any direction and you're probably hit with an advertisement, a quick tip, a savvy money narrative to digest, or perhaps even an enthusiastic stranger who swears they'll grow your wealth.

Meanwhile, your mind lingers with questions involving your personal finances that remain unresolved: "Who can I go to for advice?" "Who can I trust for help?" "What financial services address my most urgent needs?"

Certainly, there are many simple steps you can take to set yourself up for a successful financial path. If you're on top of your monthly budget and aware of your incoming and outgoing money flows, you're in better shape than many physicians. With limited time to dedicate to personal financial planning, this is about as far as most of us get. The good news is there is expert and experienced help available — the real challenge may be knowing what you're looking for and how to ask for guidance.

Let's assume you've got a pretty good idea of where you're at financially, meaning you possess a general idea of how much debt you've accumulated to this stage of your career and are bringing home enough income to make ends meet. However, you're looking to avoid financial mistakes, save money more efficiently, invest money and chart a healthy course for the years ahead. It may be time to find a financial planner and access other financial professionals.

Our research shows that e many physicians turn to existing relationships when seeking professional financial support. Referrals often come from family members, fellow residents and colleagues, neighbors, and friends. In most cases, this is how financial professionals are introduced to early-career physicians and attendings. Alternatively, physicians know that having a white coat almost immediately attracts financial advisory service professionals — haven't we all been approached, often repeatedly? Some of us are fortunate to find prudent, qualified professionals by these methods. Others aren't so lucky, and sadly feel preyed upon.

For those still looking for financial planning and other specific financial advisory services, we'll lay out some considerations which we hope are helpful. Before diving deeper into specific services, let's look at some typical services needed at various career stages in medicine.

If you're a resident, you'll probably be best served by advisors that can assist with the following: debt repayment strategies (student loans and consumer debts), budgeting and saving prioritization, insurance services (disability and life), tax and estate planning services.

For attending physicians, the previous services remain applicable with additional recommendations for retirement plan-

ning, investment management and educational savings for children. As your career progresses nearer retirement, it's certainly advisable to seek financial advice involving retirement income, long-term care planning, and post-career specific financial services.

As medical professionals, we know the value of expertise and specialization. We can similarly use this framework when seeking a financial professional. When searching for an advisor who can look holistically at your (or you and your family's) circumstances, find out how experienced they are at working with physicians. Don't hesitate to ask them for their track-record with healthcare professionals, how they think through some of the financial situations facing medical professionals, such as sizable educational debt and the need for disability insurance. Furthermore, find out if they (along with their firm) provide a full suite of services (planning, tax, insurance, etc.) or if they specialize in one area primarily. Some physicians may prefer a one-stop shop, while others feel confident in having various professionals focused on fewer aspects of finance working together toward a healthy financial future.

If you're encouraged that a prospective financial professional is competent (i.e. experienced) working with physicians and physician families, here are some additional determining factors to consider:

COMPENSATION MODEL: Know how your agent/advisor is paid for their services.

We suggest aiming to find a **Fee-Only** advising arrangement, particularly for planning services. The National Association of Personal Financial Advisors takes the position that the **Fee-Only** method of compensation is the most transparent and objective method available. This model minimizes conflicts and ensures that your financial planner acts as a fiduciary. Fee-Only planners are compensated directly by their clients for advice, plan implementation and for the ongoing management of assets. Fee-only financial advisors may be paid hourly, as a retainer, as a percentage of assets under management, or as a flat fee, depending upon the planner you choose.

Additional compensation models include fee-based (set fee for the client, additionally an agent may receive compensation from other sources, such as a commission for sale of the financial product) and commission-based (agent receives compensation from products sold to client). *One note on the insurance services: you're likely to encounter **commission-based** models in this area. Given this commonly used compensation structure in this industry, we suggest an emphasis on finding proper coverages and quality agents over a determination based solely on an agent's compensation model. More on this below.

One easy way to check for transparency is to find out if an agent is always a fiduciary. In other words, is the advisor obligated to do what is always in the client's best interest? You may be surprised to learn that even fee-based advisors, in some cases, may alternate between the suitability standard (their recommendations only need to be suitable for a client's situation) and the fiduciary standard.

TAX STRATEGIES: I need a tax strategy?! The answer is probably yes.

Unless you finished medical school while earning your CPA on the side (highly improbable) or have a personal accountant and tax preparer as your partner, you'll probably need help here. Similar to finding a financial planner, make sure you find an agent experienced with physician personal finances. The reasons for a tax strategy and consulting with a capable, licensed tax advisor are underscored here:

Tax laws, both at federal and state levels, are ever evolving. A plan which considers deductions and capital gains not only for this tax-year but also subsequent tax years will save you money.

If your household has multiple income sources, certainly you'll need a tax plan with a comprehensive approach, and an agent to advise you through the filing process.

INSURANCE SERVICES: Why choose an Independent Advisor?

An important component of a physician's financial health and financial security will be insurance services, and we strongly urge you to consider an independent advisor when seeking help in this area. The marketplace for insurance policies is wide and an independent agent is best suited to shop the offerings of various companies on your behalf. An independent advisor can walk you through the nuances of policy language, help with determining sound coverages personal to your needs, and highlight key factors for choosing the best company to work with (age, gender, specialty, benefits, etc.). Moreover, an independent agent will not have loyalties to any specific company nor any economic ties to a specific insurer.

If finding trustworthy and competent financial advisors seems bewildering, know that you are not alone. If relationships nearest you (family, friends, colleagues) make introductions to qualified financial professionals, count your blessings! And if you're still wondering how to get this kind of help and not turn prey to rent-seeking financial resources, we hope this article will focus your efforts toward finding fiduciary and fee-only service providers with a focus on transparent client relationships.

This article is authored by co-founders of ScrubMoney, a physician-created and physician-focused mobile app aimed to make sure every physician in the US healthcare system has a strong financial plan so they can better focus on healing their patients and living their lives.

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to Lana'i, with Love

SERENITY IS NOT SILENCE
LISTEN, AND I'LL ALWAYS BE WITH YOU - LANA'I

BY BRANDI BROWER

A geography lesson: Lana'i is in the middle of the Hawaiian archipelago, the sixth largest island and the smallest publicly accessible inhabited in the chain. The colloquial name is Pineapple Island because of its history as the world's largest pineapple plantation. Before pineapples, there were cattle, and before that, sugar. The island has just over 3000 residents, no fences, only one charming town, Lanai City, and not a single street light.

Today, the island commodity is no longer beef or sweet tropical fruit but hospitality. Of the 90 thousand acres, 97 percent shares of the island were purchased in 2012 by billionaire business magnate and Oracle tech founder Larry Ellison for 300 million. He has invested an estimated 600 million in the island's tourism infrastructure, including the complete renovation of the Four Seasons Resort Lana'i. Situated on the southeastern shores of the last unspoiled island of Hawaii rests the exotic and serene resort on top of the red-lava bluffs overlooking the protected marine preserve Hulopo'e Bay and its pristine beach.

The remote island is a world away from the built-up and popular Hawaiian destinations like Maui and Oahu. Lana'i is an ideal climate year-round, hot and sunny by the ocean and a bit cooler in the Upcountry and Lana'i City. Because of trade-wind clouds captured by the high mountains on neighboring Maui, the near-desert ecology receives slight rainfall. The tall Cook pines were planted on the island ridge line and along roadways a century ago because the tree needles efficiently collect dew, providing much-needed water for the dry climate. Each tree contributes 200 gallons of water to the island daily, all taken right out of thin air. Palm trees are on Lana'i, but the island is surprising with its abundance of pine trees and the patchwork of plant species arrayed across the landscape.

One of the first things that strike you as you fly over Lana'i is how different it is compared to the tall buildings dotting the highly populated Honolulu or the lush green rainforests of Kauai. "You must look to the past to move forward," is a Hawaiian saying. Parts of this little island are so untouched that you feel like you have returned in time, 100, 200 years, or more. Larry Ellison has chosen to look back and preserve the peace and tranquility of the land and move forward with the many progressive changes and enhancements to his piece of paradise.

With only 30 miles of paved roads, no box stores, fast food, or shopping malls, it feels like a remote destination. Once you arrive at the ultra-lux Four Seasons Resort Lana'i, you soon discover the hotel manages all the on-site activities and off-site excursions to ensure the highest level of service during the stay. Amenities and adventures on the island are not run by a third party but are owned and coordinated through the Four Seasons, and the opportunities for adventure and relaxation abound. To escape the everyday mundane and frolic in flora and fauna of a billionaire's private island is a reset we can all respect.



The short 20-minute flight from Oahu and the additional 20-minute shuttle to the Four Seasons property is a seamless transfer coordinated by the resort. A warm grin and "Welcome to 'La-nah-ee'" from my greeter Ned, as he puts a beautiful lei around my neck. My mind focuses on the fact that I have been miss pronouncing the island name, Lana'i, as in a veranda. I practice the correct phonetics in my head until I'm stopped in my tracks by the expansive two-story lobby with its gorgeous wood floors, plantation-shuttered windows, coffered ceiling with glass to allow sunlight in from above, large planters with palm trees, substantial muraled storyboards of the island's history flanked to the left and right. It opens to a living area below, with two separate staircases descending to the lower level. Beyond is the incredible patio and gateway to the breathtaking vista of Hulopo'e Bay and beyond. I'm impressed with the sleek esthetic blending of contemporary furniture and old Hawaiian chic. On display, a beautifully restored 19th-century Koa Wood outrigger canoe, an archival piece in the great hall, looks like it should be on a vintage postcard. Reception is quick and kind as Jessie Lin tours the facilities and takes me to my guest room.

Only the best state-of-the-art technology will do when a tech giant renovates a resort. Guests receive flexible, waterproof RFID wristbands instead of key cards, so they don't have to worry about losing keys while on an excursion or exploring the ocean. The bedside iPad Air is the equivalent of a butler allowing you to do everything, from housekeeping to summoning room service, to controlling the lighting in the bedroom, bathroom, and patio, and enjoying free wifi. The lighting control panel has various mood settings, such as 'relax,' 'sunset,' or 'nightlight.' Even the bathrooms have high-tech features, such as a TV embedded in the vanity mirror and motion-sensing Toto bidets. The 75" LCD television is a room feature, but with the beautifully



furnished patio and nature as entertainment, it's probably rarely used.

With Mr. Ellison's affinity for Japanese culture, there is a "wow" factor when entering the suite. The guest rooms are innovative and elegant, with zebra wood, teak, grasscloth, and stylized wallpaper with Nepalese Lokta designs. No surface was left untouched. Even the ceiling has exciting design elements. No detail is spared in the hand-woven wool area rugs, Hokkaido ambient lamp, or a giant Koi fish nightlight as a focal piece. The spacious bathroom is lux with slate floors, double vanities, a large shower with rain head and pebbled floor, or marble encased soaking tub for relaxing while enjoying the Lather brand "farm to tub" products, a co-creation specific to the resort, a socially and environmentally advanced bath and body collection. Then there are the Four Seasons' high bar standards of robes, beds, and pillows; need I say more?

There are 213 guest rooms, 45 of which are suites. The rooms are all within a series of low-rise buildings attached to the main house. A walk to the guest room via open hallways, you are surrounded by verdant lush gardens, koi ponds, waterfalls, art pieces, sculptures, and intimate gathering spots with couches and comfy chairs in outdoor enclaves. In every direction you look, there's beauty. Whether your guest room has a garden view, ocean view, or view of the marine sanctuary, all are amazing. Every room has turn-down service, beautiful fresh flowers, and a "welcome to our slice of paradise" pineapple treat upon arrival.

This special serene place offers privacy and tranquility or fun and adventure. I take advantage of both worlds. My first adventure was to check out the Manele Golf Course, a Jack Nicklaus-designed premier 18-hole golf course, a par 72 on a track just over seven thousand yards. Situated just above the Four Seasons resort, the golf architect had gorgeous land to work with high on the rugged lava cliffs and hills above the shimmering sea below. Many courses around the world can boast select signature holes with ocean views. But the Lana'i Manele Golf Course has bragging rights to ocean views on every hole. What a spectacular setting and memorable backdrop whether you are driving, putting, or everything stroke in between. One particularly scenic spot, the 12th hole, a par three, is the famous spot where Bill and Melinda Gates were wed.

As the twilight hour approaches and the tiki torches are about to be lit, I take a five-minute walk down the path that follows Hulopo'e Bay to breathe in the beautiful sunset. The beaches in Hawaii are all public, but the Four Seasons resort has a section with umbrellas, chairs, and beach service for its guests. While walking along the water's edge, I passed a little girl who waved and said, "Aloha, Auntie!" The kind greeting takes me aback. I later learned in the Hawaiian culture, calling one an auntie or uncle is a sign of respect toward elders. What a sweet gesture from a young stranger. I'm beginning to feel the Lanai love.

Adventure Park has many choices for thrill seekers; obstacle course, zip lining, and aerial tower, but I choose the e-bike tour to begin my first full day. After getting fitted on my Quietkat bike, a helmet, and an introduction to my two guides and group, we take off on our red dirt excursion. The ride takes us past the Lana'i Ranch at Koele, where you can ride horseback or visit miniature horses and other animals. Other Four Seasons activities for an adrenaline rush include sporting arrows, archery, sporting clays, and a rifle experience. My aim isn't great, so I lean into cycling instead. The bike trek is to the heritage site, and scenic outlook of Keahiakawelo, nicknamed the "Garden of the Gods." The ride ascends to the top, where large red boulders, clay formations, and very little, if any, vegetation gives the impression that we have arrived on the red planet of Mars. With views of Maui and Molokai and the outline of Oahu on a very clear day, it's a fantastic vantage point. The guide shares the story of the hallowed spot in what Hawaiians believe is a sacred place.

After the lunar landscape visit and the trek back, I spend some relaxing time poolside. There are two options for sun leisure on-site, a family pool area and a more private gated area for adults only. Both offer jacuzzis and waterfall features, but the adult pool has a grotto vibe with lava rock mimicking the island's dramatic cliffs. The pool attendant guides me to a spot with a beautiful bay view, prepares a lounge chair covered in a thirsty towel with a headrest, and adjusts the umbrella. I'm given a menu for lunch options from Malibu Farm, a fresh farm-to-table franchise that fits the resort's food philosophy: know your farmer, know your food. Four Seasons Resort Lana'i supports more than 100 local farmers and fishers; approximately 65 percent of the menu items come from the Hawaiian islands. I decided on the fish tacos, local catch of the day with roasted salsa, cucumber creme fraiche, and cilantro on corn tortillas. I'm tempted to order the deliciously rumored grilled chocolate cake with sea salt and caramel sauce as an indulgence. But I opt for the mango popsicle treat the attendant offers each pool guest.

Late afternoon, not too sunburned, I'm on a five-minute ride down to the marina. The small group of us arrive at the 65' sloop-rigged sailing catamaran Lana'i II for our sunset sail over the Pacific along the island's coastline. On the cruise out, we concentrated on looking for breaching whales; it's at the end of their season. A crew member



puts a microphone down through the roped netting of the boat, and we hear the haunting sounds of a nearby pod of humpback whales. Both males and females make sounds, but the males produce the species' loud, long, and complex melodies. We were on their trail, and it wasn't long before we could witness one breaching the surface. We enjoyed the appetizers and drinks served as we turned back toward the setting sun, capturing the moments with our phones as the colorful rays dipped into the ocean. The time on the water, experiencing nature at the moment as spinner dolphins frolic in the surf is transformational. The love for Lana'i is growing.

With the sounds of the ocean below and the ambient garden lighting, Ben has seated me at a lovely table for dining. Named after the number of square miles on the island, restaurant One-Forty is known for its hearty menu items and doesn't disappoint. My starter, Ali'i mushroom soup, as I have learned in my experience with Four Seasons chefs, their soups are unbelievably good. The crispy shitake mushrooms, macadamia, creme fraiche, truffle oil, and chives combined were no exception to that fact. I opted for beef with the prime filet, and the most delicious sauces of chimichurri, rosemary demi, tarragon bearnaise, and signature One-Forty steak sauce enhanced the main course. Some grilled asparagus and charred creamed corn with applewood smoked bacon as sides, and my tastebuds are happy.

Another dawn breaks, another beautiful day ahead, and I stop at The Break restaurant for a quick acai bowl before my next excursion—an excellent place for either sit-down American classics, Poke bowls, and local specialties or grab-and-go bites. I'm excited about the itinerary: snorkel sail. The fleet of Lana'i Catamarans is impressive in size and sleekness, and I'm lucky enough to procure a spot on the "trampoline" roped netting to lay on while we sail to



Kaunolu Bay (Shark Fin Cove.) With equipment on, the group explored depths of 10 - 50 feet, snorkeling in "the bay" and "the fin," which gleaned its name from the rock shaped like a shark's dorsal fin protruding out of the water. The underwater life is vibrant, with large schools of reef fish, parrotfish, and a few eels. After we come aboard the vessel, lunch is served, and I'm struck by the immense sea cliffs we are anchored near—some of these cliffs reaching 350 feet high, the second tallest in the world. The sport of cliff jumping, known as lele kawa, was reserved for Hawaiian royalty who possessed so much mana, or strength, that they could throw themselves off of sacred promontories where it was believed that souls would be transferred from this world into the next—so much history and beauty here to soak in.

Back on land, I walk the paths to appreciate the natural and consciously crafted gardens around the resort. Director of Landscaping, Robert Woodsman, carefully curates the beauty of the property's botanical gardens. He feels the landscapes are equally crucial to the design of the buildings, presenting a wonderful harmony throughout the resort. "Guests meander through a setting that is not your standard arrangement of basic plants and generic landscape design, but rather a collection of plants mostly seen in botanic gardens or private collections." Woodsman continues, "It is almost like you experience the greenery as a guest staying in someone's private home, curated with great care and love."

I venture beyond the pristine beach of Hulopo'e Bay, past the tide pools on the eastern side, and hike up the trail towards one of the island's most famous natural landmarks, Pu' upehe, known as Sweetheart Rock. Not only does the climb reveal stunning views of the hidden beaches and sea caves below and the sprawl of the Four Seasons Resort in the background, but as with every lovely thing on the island, the 80-foot red rock rising out of the sea is steeped in Hawaiian folklore. Legend says a heartbroken warrior Makakehau, loved a woman named Pehe. Devastated when a storm surge killed her, he pleaded with the gods to help him scale the 80-foot rock and carry Pehe's body to the top for burial. Overcome with grief, he jumped from the summit into the pounding surf below to his death. All for love.

Four Seasons Resort Lana'i is a multi-award-winning resort annually. So many amenities I have yet to highlight that contribute to their honors: The Hawanawana Spa offers unique treatments inspired by the ocean's healing powers, Nobu Lanai' restaurant, cuisine of world-renowned chef Nobu Matsuhisa, with intimate sushi counter and several teppanyaki setups (where food is cooked table side), the 24-hour fitness center features state-of-the-art cardio and weight-training equipment and tons of natural light with the gym's massive arched windows overlooking the ocean and garden grounds, free Kids For All Seasons program where guests ages 5-12 can participate in activities like tidal pool exploration, build-your-own volcano workshops, lei-making, and hula lessons, rent a Jeep for off-roading, 4×4s made for an off-the-beaten-path adventure, the resort's tennis courts which consist of two Plexipave courts and one Har-Tru green clay court, take advantage of the zero light pollution with stargazing in the hotel's new observatory, which houses a 40-inch telescope, and opportunities to experience culture at every turn with ambassadors like latter-day legend "Uncle Bruno" who shares stories of his island while teaching traditional lauhala weaving, lei making, ukulele playing or hula.

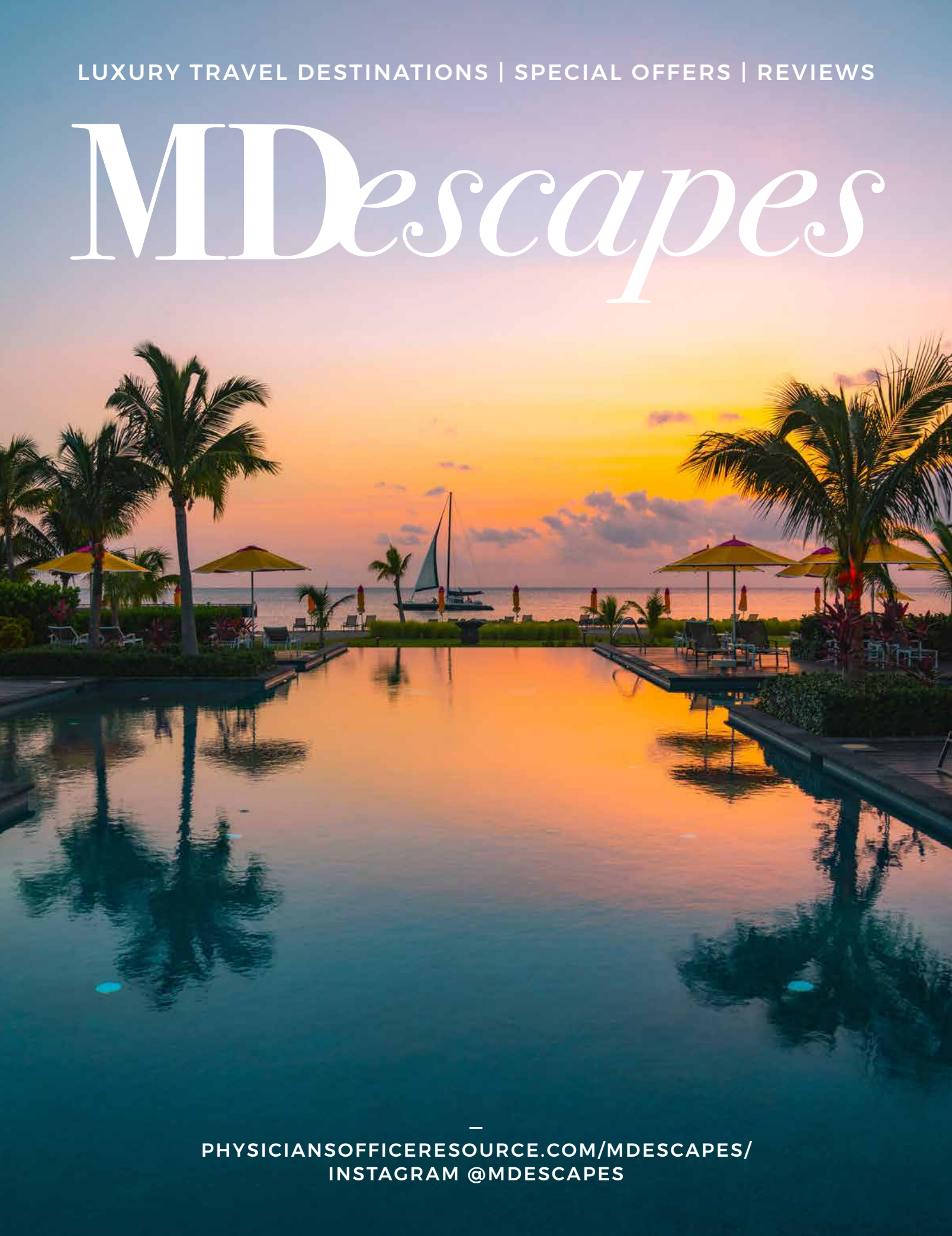
Every evening, a Lana'i ambassador, dressed in traditional attire, runs out to the patio and blows the conch shell ceremonially four times, once in each direction. Afterward, in the great hall, guests enjoy a hula performance. Lana'i is a special place. A magical place. An island like no other.

"E ho'okipa me ke aloha." Which translates to: "Host with love and compassion." The spirit of Na Mea Ho'okipa is unconditional aloha spirit, hospitality from within. Samson, a Lana'i ambassador, explained this spirit of aloha while he patiently taught me how to make a plumeria lei. "What makes Lana'i so unique?" I asked. He explained, "Everyone on the island knows each other, respects one another, and is happy to serve side by side. Mid-thought, he pauses, smiles, and nods to one of his team members. "We're neighbors, family, and friends working to share our aloha with you."

It is written: "To know Lana'i is to love Lana'i. We ask only that you be in the right spirit to listen, to learn, and to respect the island's gifts that are so readily available to our guests. Follow your passions beyond your comfort zone and feel the aloha spirit of Lana'i locals as they share the honored rituals of our forefathers. Our island sanctuary awaits your arrival. We joyfully prepare to welcome you."

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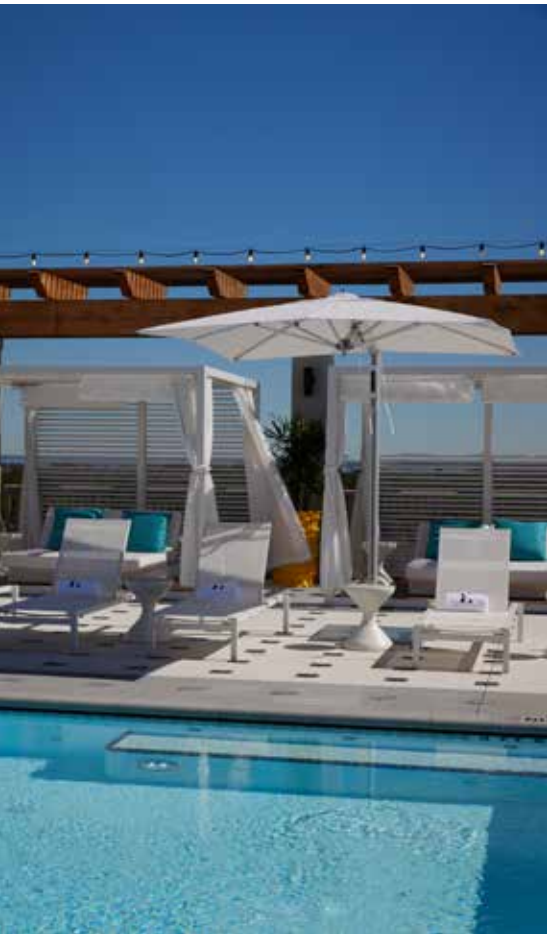
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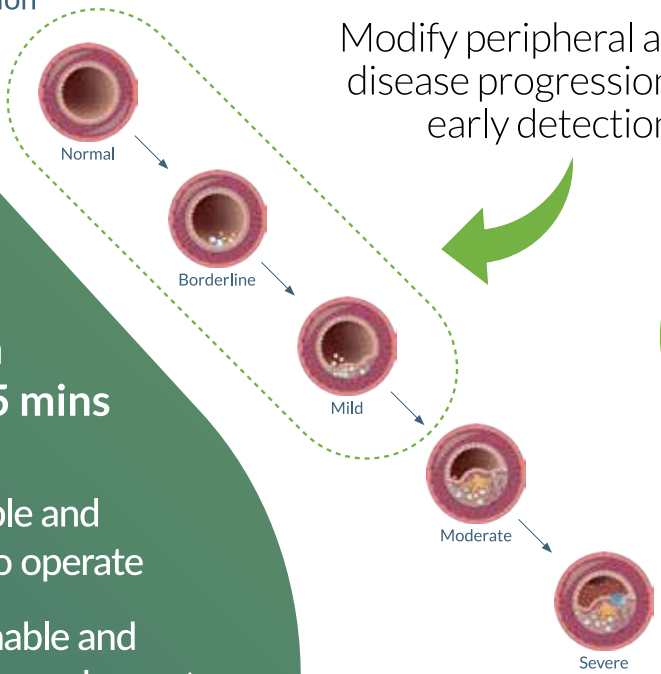
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