2023 | Issue 10

Physicians office Resource

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THE LONG HAUL:

POSSIBLE NEW EXPLANATION FOR LONG COVID



MDescapes — WHERE EAST MEETS BEST FOUR SEASONS HOTEL TOKYO AT MARUNOUCHI
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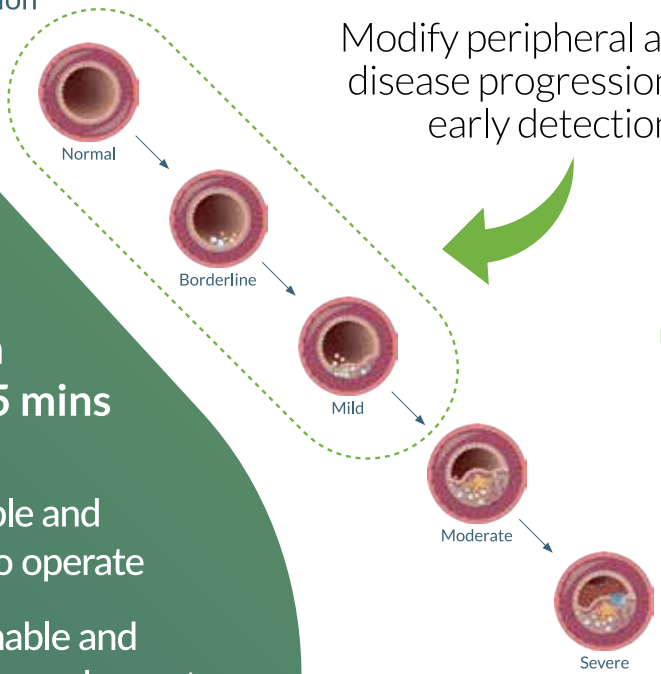
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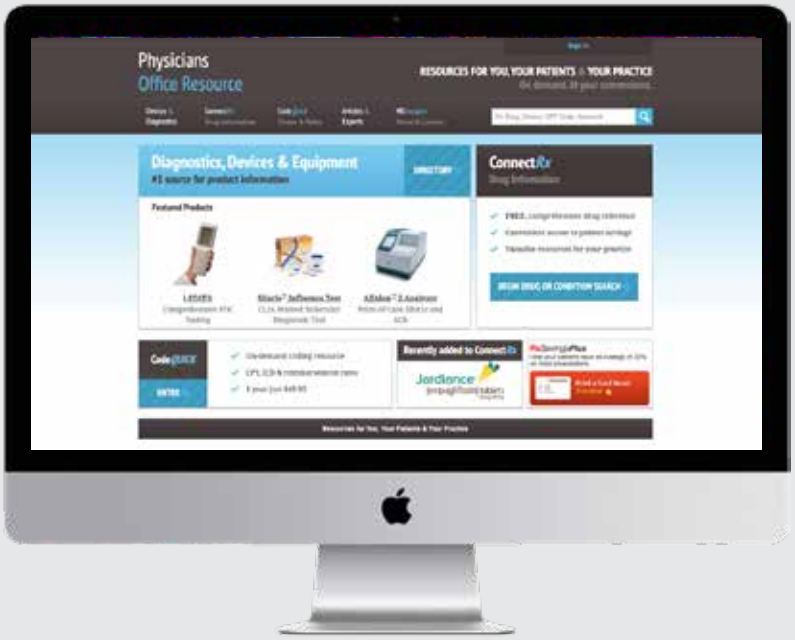
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*2016 AHA/ACC Lower Extremity PAD Guidelines: Age ≥ 65y; Age 50-64y, with risk factors for atherosclerosis; Age <50 y, with diabetes mellitus; and one additional risk factor or atherosclerosis[1]

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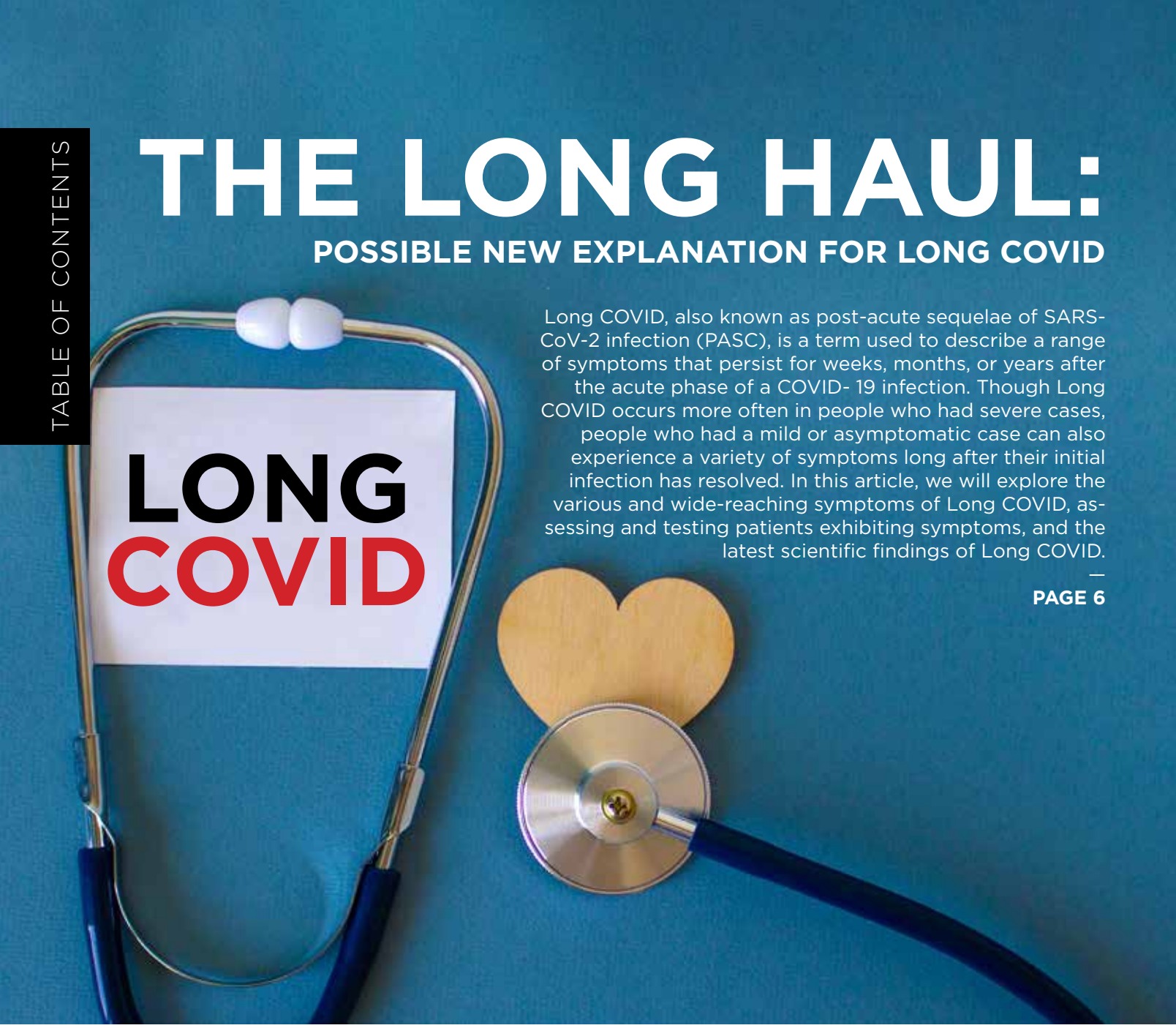
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POSSIBLE NEW EXPLANATION FOR LONG COVID



Long COVID, also known as post-acute sequelae of SARS-CoV-2 infection (PASC), is a term used to describe a range of symptoms that persist for weeks, months, or years after the acute phase of a COVID- 19 infection. Though Long COVID occurs more often in people who had severe cases, people who had a mild or asymptomatic case can also experience a variety of symptoms long after their initial infection has resolved. In this article, we will explore the various and wide-reaching symptoms of Long COVID, assessing and testing patients exhibiting symptoms, and the latest scientific findings of Long COVID.

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THE LONG HAUL: POSSIBLE NEW EXPLANATION FOR LONG COVID

BY AARON MEDARIS,
PHYSICIANS OFFICE RESOURCE



Yes, we're still talking about COVID. We wish we didn't have to, but the fact is, COVID is here to stay and it's something we're going to have to deal with. Luckily for us, the past 3.5 years have been filled with technological advancements that help us better test, prevent, and treat this cruel illness; allowing many people who contract COVID-19 to recover in a matter of days or weeks. However, there are some people who have been infected that experience long-term effects from their infection, known as Long COVID. Long COVID, also known as post-acute sequelae of SARS-CoV-2 infection (PASC), is a term used to describe a range of symptoms that persist for weeks, months, or years after the acute phase of a COVID-19 infection. Though Long COVID occurs more often in people who had severe cases, people who had a mild or asymptomatic case can also experience a variety of symptoms long after their initial infection has resolved. In this article, we will explore the various and wide-reaching symptoms of Long COVID, assessing and testing patients exhibiting symptoms, and the latest scientific findings of Long COVID.

Symptoms of Long COVID

As of today, there are no diagnostic tests that determine if a patient's symptoms or conditions are due to Long COVID. Symptoms and conditions can be wide and far reaching and, in some cases, they can even go away and then come back. Common symptoms associated with Long COVID can include:

- **Fatigue:** Persistent and often debilitating tiredness or weakness.
- **Shortness of Breath:** Difficulty breathing or breathlessness, even during mild physical activity.
- **Cognitive Issues:** Often referred to as "brain fog," which can involve difficulties with concentration, memory, and mental clarity.
- **Muscle and Joint Pain:** Widespread or localized muscle and joint aches or discomfort.
- **Chest Pain:** Discomfort or pain in the chest, which may be associated with breathing difficulties.
- **Headaches:** Frequent or severe headaches.
- **Loss of Taste or Smell:** Anosmia (loss of smell) or ageusia (loss of taste).
- **Sleep Disturbances:** Problems with sleep, including insomnia or excessive fatigue.
- **Heart Palpitations:** Irregular or rapid heartbeats.
- **Gastrointestinal Symptoms:** Digestive problems, such as diarrhea or abdominal pain.
- **Skin Rashes:** Skin issues or unexplained rashes.
- **Dizziness:** Feeling lightheaded, dizzy, or experiencing vertigo.
- **Mood Changes:** Emotional and psychological symptoms, such as depression, anxiety, or mood swings.
- **Fever:** Occasional or persistent low-grade fevers.
- **Post-Exertional Malaise:** Severe fatigue or worsening of symptoms after physical or mental exertion.

It's important to note that the duration and severity of these symptoms can also vary widely. Some people experience mild, manageable symptoms, while others may have more severe and debilitating symptoms that last for months. Additionally, new symptoms may emerge over time, making long COVID a complex and challenging condition to manage.

Assessing and caring for those with Long COVID

Many Long COVID conditions can be diagnosed clinically based on history and findings on physical examination. Others might require directed diagnostic testing, however it is important as a healthcare provider, to help the patient understand that such clinical assessments might be uninformative. Because Long COVID conditions involve multiple organ systems, a thorough physical exam should be considered. In addition to blood pressure, heart rate, respiratory rate, pulse oximetry, body temperature, and body mass index, healthcare providers should evaluate ambulatory pulse-oximetry for patients with respiratory symptoms, fatigue, or malaise. For patients experiencing postural symptoms such as dizziness, fatigue, or cognitive impairment, Orthostatic vital signs should be evaluated.

Utilizing laboratory tests can be informative, but again it's important for the patient to understand that there is no "one" test that will determine if they are experiencing Long COVID. However, because Long COVID affects multiple organ systems, laboratory tests may be able to help you as a provider better un-

Basic Laboratory Tests to Consider with Long COVID patients include:

CATEGORY	LABORATORY TESTS
Rheumatological Conditions	Antinuclear antibody, rheumatoid factor, creatine phosphokinase, anti-cardiolipin, anti-cyclic citrullinated peptide
Coagulation Disorders	D-dimer, fibrinogen
Myocardial Injury	Troponin
Differentiate symptoms of cardiac vs. pulmonary origin	B-type natriuretic peptide

Specialized Diagnostic Laboratory Tests to Consider with Long COVID patients include:

CATEGORY	LABORATORY TESTS
Blood count, electrolytes, and renal function	CBC with possible iron studies, basic metabolic panel, urinalysis
Liver Function	Liver function tests or CMP
Inflammatory Markers	C-reactive protein, erythrocyte sedimentation rate, ferritin
Thyroid Function	TSH and free T4
Vitamin Deficiencies	Vitamin D, vitamin B12

derstand how Long COVID may be affecting your patient.

Other assessment tools can be utilized for evaluation of patients with Long COVID conditions. Testing should be adjusted to fit the patients symptoms and presentation. Those assessments can include the following:

Functional status or quality of life
Patient Reported Outcomes Measurement Information System
Post COVID Functional Status Scale
EuroQol-5D

Respiratory Conditions
Modified Meical Research Council Dyspnea Scale

Neurologic Conditions
Montreal Cognitive Assessment
Mini Mental Status Examination
Compass32
Neurobehavioral Symptom Inventory

Psychiatric Conditions
Generalized Anxiety Disorder-7
Patient Health Questionnaire-9
PTSD Symptom Scale

Latest Findings on Long COVID
In a recent study published in the journal Cell, scientists from the University of Pennsylvania discovered that serotonin levels were lower in people with symptoms of Long COVID. These researchers are suggesting that lingering effects of the COVID-19 virus reduce the amount serotonin the body produces.

In this study, researchers analyzed the blood of 58 patients dealing with Long COVID symptoms between 3 and 22 months since infection of the virus. That blood was then compared to 30 people who experienced no Long COVID symptoms in addition to 60 patients in the early stages of a COVID-19 infection.

One finding that stood out to Maayan Levy, a lead author on the study and professor at Perelman School of Medicine, was that levels of serotonin and other metabolites were altered right after a COVID-19 infection, something that also happens immediately after other viral infections. However, in patients with Long COVID, serotonin was the only significant molecule that did not recover to pre-infection levels.

The researchers also analyzed stool samples from some of the Long COVID subjects and found that they contained remaining viral particles. Utilizing this knowledge, researchers turned to miniature models of the human gut, knowing that this is where more serotonin is produced, and were able to identify a pathway that could underlie some cases for Long COVID. The thought behind this pathway is that viral remnants prompt the immune system to produce interferons. These interferons cause inflammation which inhibits the body's ability to absorb tryptophan (amino acid that helps produce serotonin). This can trigger blood clots after a COVID-19 infection and could impair the body's ability to circulate serotonin. With lower levels of serotonin within the body, the vagus nerve is disrupted and therefore the parasympathetic nervous system is also disrupted.

Scientists also proposed that patients exhibiting symptoms of Long COVID due to lower levels of serotonin could also be an explanation of why they experience problems with short-term memory, as serotonin plays an important role with memory.

Though this study shows promise, researchers understand that this study needs to be enlarged to be more definitive in its results. An expansion of this study will most likely focus on the three biomarkers presented in this study: the presence of viral COVID remnants in stool, low serotonin, and high levels of interferons.

"All these different hypotheses might be connected through the serotonin pathway," said Christoph Thaiss, lead author of the study. "Second of all, even if not everybody experiences difficulties in the serotonin pathway, at least a subset might respond to therapies that activate this pathway," he went on to say.

Dr. Levy and Dr. Thaiss, both researchers in this study said they would begin clinical trails to test the effectiveness of fluoxetine (Prozac) which is a selective serotonin reuptake inhibitor to see if they can restore some of the vagal signals to improve memory and cognition.

Time will tell what the results of the clinical trials will be. Until then, it's important as a healthcare professional to listen with compassion and support your patients that struggle with Long COVID. Assess, diagnose, and provide them with the resources that can help them through this difficult time.

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Caring for People with Long COVID
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PAGING ALL RESIDENTS:

WHO'S LOOKING OUT FOR YOUR FINANCIAL WELLNESS?

If your wallet needs live-saving measures, now is a great time to avert a crisis.

BY ANDY HARMS

The grind. Residents know about it. Long days requiring intense mental focus. Physically demanding. Exhilarating and enjoyable, yet exhausting and overwhelming at times. Loving what we do—but not loving what it does to us on some of those days.

We're a diverse set of people yet bound together by purpose. We can thrive in ever-changing, always-evolving patient care environments and on-call opportunities. Just as well, many of us excel best with a more structured day, one with meticulous order and greater command over outcomes. Our personal identities and varied interests were a large part of how we chose our specialty.

Regardless, as residents we've all been trained to think on our feet, orient and analyze quickly, decide with assurance, and act toward a favorable outcome.

In speaking with residents over the years about personal financial situations, I see an incredible ability for young physicians to manage—if not juggle! —their money matters despite weighty, disorderly, and persistent challenges.

Wouldn't it be nice if there was an easier way to prepare and plan financially, to bring order from chaos? The good news: there IS a better way. The bad news is you likely were NOT trained in finances the same way you trained for medical practice.

The Journal of the American College of Surgeons published a study in 2018 titled "Clinically Competent and Fiscally at Risk: Impact of Debt and Financial Parameters on the Surgical Resident." One hundred five resident trainees were surveyed on topics of personal finance, and the majority (79%) of respondents felt strongly that inclusion of additional financial training in residency education is a critical need. The authors conclude: In a climate of increasingly delayed financial gratification, surgical trainees are on critically unstable financial footing. There is a major gap in current surgical education that requires reassessment for the long-term financial health of residents.

In digging deeper for perspective on resident finances, I spoke with the researcher and author of this study with the longest tenure in medicine, Dr. Bruce Harms, MD, MBA, FACS. "My generation of doctors, I believe, assumed that we could out-grow, with time, any financial mistakes and miscalculations we made in residency and early on in our careers. I think that is an incorrect assumption nowadays. For younger docs, in this era, the mistakes made from a financial standpoint may be extremely costly in the long run." When asked to point out the biggest differences from

then (Dr. Harms began residency in 1978) to now, he pointed out "certainly educational debt is the biggest difference I see, but also the cost of living. Housing, transportation, health care and childcare command a significantly greater part of a budget as compared to when I received my start in medicine."

If you're in a residency program that addresses your financial literacy and financial preparation needs well, count your blessings. That's certainly not common throughout organized medicine in the United States. Similarly, if you're employed in a residency program that offers a retirement plan with matching employer contributions, count yourself fortunate.

So where can we turn for assistance to avoid making costly financial mistakes and confidently face the challenges of personal finance during residency, given it may be unlikely to come through our employers or GME programs?

One of my favorite recommendations for residents hoping for better command over their personal finances is to pick up, digest, and implement suggestions from a book titled MD in the Black: A Personal Finance Primer for Medical Residents. (Please note: I have no ties to the authors or sponsors of this book) It's informative, practical, and concise. For all those in the TL;DR camp, it's only a hundred pages. I recognize your time is limited—among the barriers to better financial literacy—but reading this book is certainly worth making a priority. Editor-in-Chief Eric Shappell, MD, MHPE, and physician educators from around the United States created a great resource, specifically designed for residents.

The book focuses on five topics: 1) Educational debt, 2) Long-term disability insurance, 3) Life insurance, 4) Investing, and 5) Financial advisors

Likely you have questions in all these areas. The authors point out "they are each related to a significant financial decision that the majority of residents will encounter during training."

We won't breakdown each major category here, of course, but I would like to highlight two takeaways that every reader of this article at the residency level should consider:

First, on the topic of educational debt: Have you asked yourself "What is Public Service Loan Forgiveness?" and "Should I Pursue PSLF?" This is the first decision you should make, and various sources can help you better understand how to approach this process of determination. Once a determination is made regarding PSLF, a debt repayment strategy can be mapped out further.

As important as long-term disability insurance, life insurance, and investing are to the needs of a resident, a personal and in-depth commentary on each is beyond the scope and space of this article. However, they are a good lead-in to the second point we'd like to highlight here from Dr. Shappell's book, considering the question "Should I Hire a Financial Advisor in Residency?"

Most residents should be able to get along just fine with only a few hours dedicated to researching the basic financial decisions of residency (1) choosing a loan repayment plan, (2) choosing which insurance products to purchase and when, and (3) what to do with any extra income (typically a decision of whether to make extra payments on loans vs. invest). If you don't feel comfortable making these decisions on your own and aren't interested in learning more about them yourself, choosing to hire a financial advisor may be the way to go. This also may be a good idea if you have unusually complex financial circumstances. (Shappell 84)

Whether during residency or as an attending, the likely outcome in any event is a search for an experienced and trusted financial advisor. What credentials do you seek, what questions do you ask? MD in the Black notes residents looking to start at the ground-level in forming a financial plan will do well to consider an advisor with a Certified Financial Planner (CFP), Chartered Financial Consultant (ChFC) or Certified Public Accountant/Personal Financial Specialist (CPA/PFS) designation. Additionally, I suggest aiming to find a Fee-Only advising arrangement, particularly for planning services. 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.

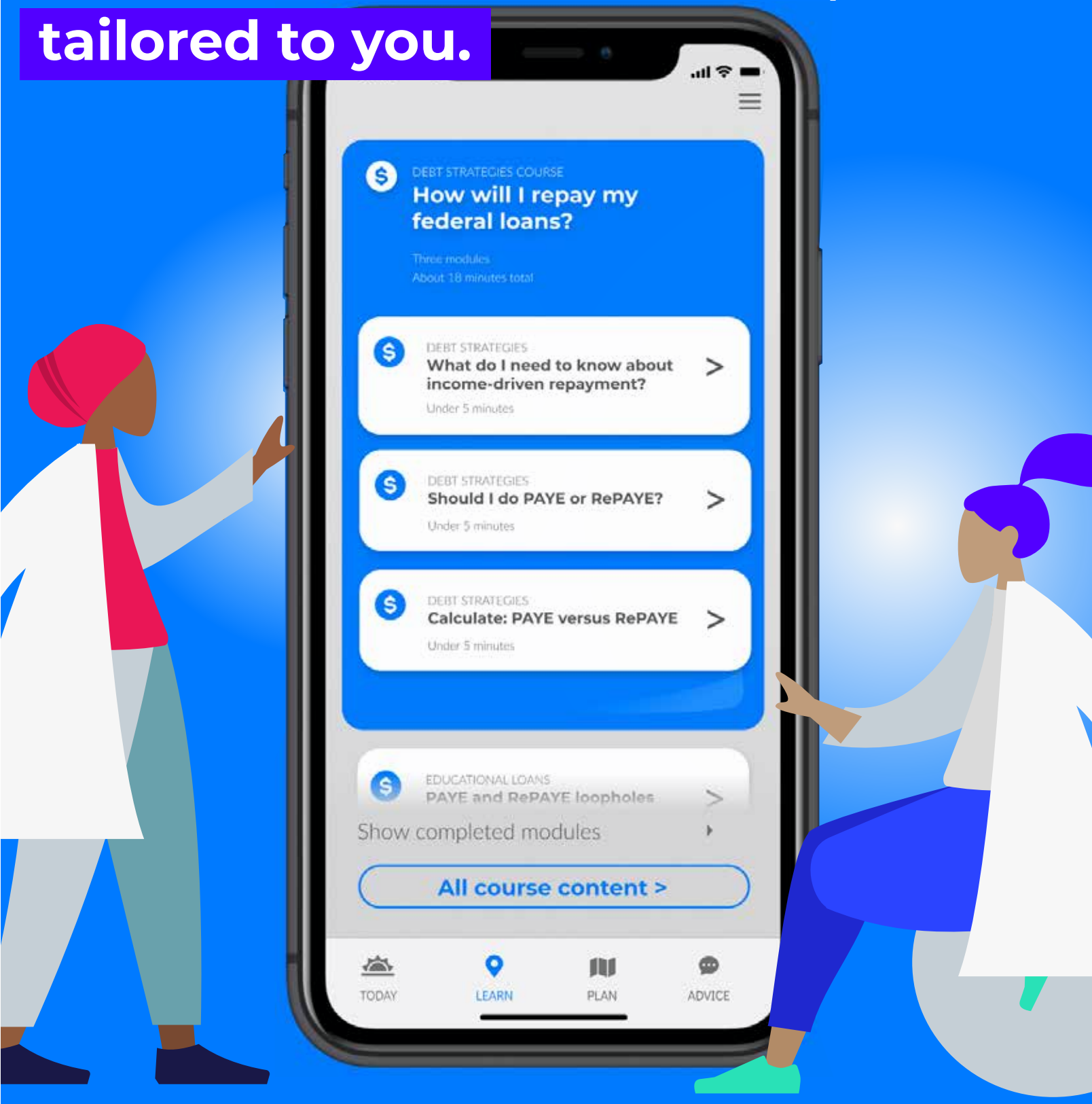
As residents, we understand the importance of preventative health care and the consequences of delayed treatment. This understanding, applied to our personal finances, will not only stave off a trip to the financial ED (i.e., more borrowing, lower net worth, less financial freedom), but enable us to enjoy the peace of mind and sense of confidence that comes with financial health. Our goal should be to confine the chaotic moments and stressors related to medicine to the hospital and away from our pocketbooks.

We invite you to check out the resources mentioned above and reach out for help at any time to gain better financial understanding, set financial goals, and establish a path to financial wellness. Residency may be the best time to reach out, while the time is still on your side.

—

Andy Harms is co-founder of ScrubMoney, a free app now available for download, providing financial literacy and relevant personal financial content. ScrubMoney aims to empower early-career physicians to achieve financial wellness and enable stakeholders in healthcare to better develop financially confident doctors within their organizations.

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

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

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POC-22-NAM-3308

Meet the Quadruple Aim in Diabetes Care with In-office HbA1c and uACR

Better outcomes. Lower costs. Better patient experience. Better clinician experience.

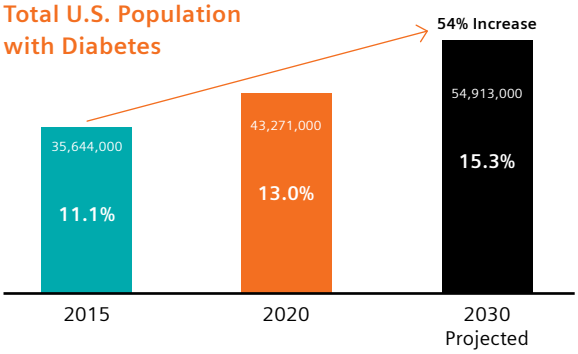


Comprehensive diabetes-management solutions at the point-of-care

Gain key insights into your patient's current status and drive guideline recommended test adherence:

DCA Vantage® Analyzer
CLIA-waived HbA1c
- Rapid assessment for glycemic control

CLINITEK Status® Connect System
CLIA-waived analyzer for routine urinalysis
- Rapid kidney health assessment:
  CLINITEK® Microalbumin 2 Strip
  Albumin-to-creatinine ratio (ACR)





The Prevalence of Diabetes Among U.S. Adults is on the Rise[1]

Help your patients reverse the trend

Customize your patient consultations to enhance physician-patient partnership toward improved outcomes.

siemens-healthineers.us/chronicdisease

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

SIEMENS Healthineers

Step into POSSIBILITY



INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

SELECT IMPORTANT SAFETY INFORMATION: WARNING RELATED TO SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS: Olumiant-treated patients are at increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Olumiant if a serious infection occurs until the infection is controlled. Olumiant should not be given to patients with active tuberculosis. Test for latent TB before and during therapy, except for COVID-19; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.

MORTALITY: Higher rate of all-cause mortality, including sudden cardiovascular death was observed with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients.

MALIGNANCIES: Malignancies have also occurred in patients treated with Olumiant. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE): Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.

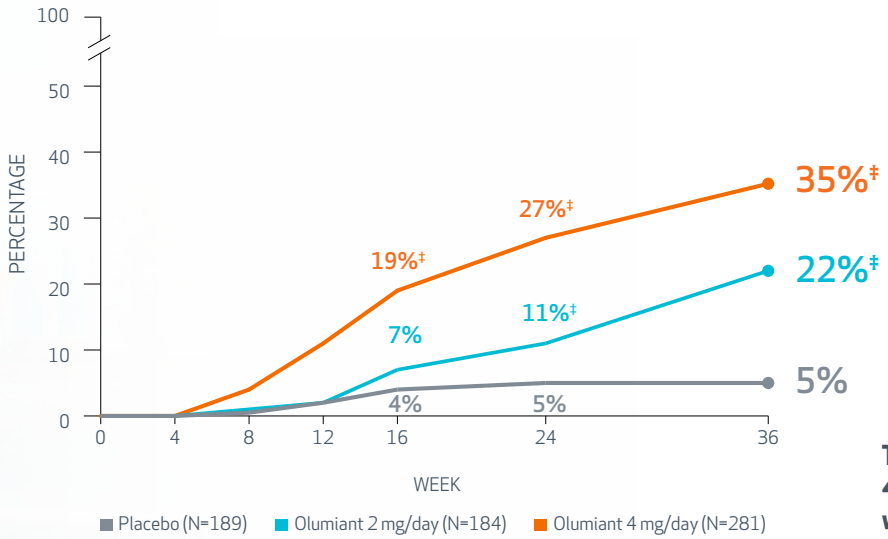
THROMBOSIS: Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.

For adults with severe alopecia areata (AA)

Olumiant can help patients regrow their hair resulting in meaningful scalp coverage at week 36[1-4*]

olumiant® (baricitinib) tablets
4 mg, 2 mg

BRAVE-AA1: Percentage of Patients Who Achieved a SALT Score of ≤20 Over Time, NRI†



BRAVE-AA2: Percentage of Patients Who Achieved a SALT Score of ≤20 Over Time, NRI†

	Week 16	Week 24	Week 36
Placebo (N=156)	1%	1%	3%
Olumiant 2 mg/day (N=156)	8%	11%	17%‡
Olumiant 4 mg/day (N=234)	18%	28%‡	32%‡

BRAVE-AA1 and BRAVE-AA2 clinical trial design[1,2]

Olumiant was studied in two randomized, double-blind, placebo-controlled clinical trials in adults with a SALT score of ≥50 and a current AA episode lasting >6 months and <8 years in duration. BRAVE-AA1 was a phase 2/3 trial that enrolled 654 patients in the phase 3 portion. BRAVE-AA2 was a phase 3 trial that enrolled 546 patients. Patients were randomized 2:2:3 to placebo, Olumiant 2 mg, or Olumiant 4 mg once daily. The primary endpoint was the proportion of patients achieving a SALT score of ≤20 at week 36.

The recommended dosage is 2 mg/day. Increase to 4 mg/day if response is not adequate. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider 4 mg/day. Decrease to 2 mg/day once patients achieve an adequate response with 4 mg/day.

*Primary endpoint was the proportion of patients achieving a SALT score of ≤20 at week 36.

†Data collected after permanent study drug discontinuation or data collected at remote visits due to the COVID-19 pandemic were excluded.

‡$p \leq 0.05$ vs placebo.

NRI=nonresponder imputation; SALT=Severity of Alopecia Tool.

*Olumiant is the **FIRST FDA-APPROVED** systemic treatment for adults with severe AA*

Explore the results at **Olumiant.com/HCP/AA**

Please see the following pages for Important Safety Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Brief Summary of Prescribing Information.

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction [MI], and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

olumiant®
(baricitinib) tablets
4 mg, 2 mg

THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials.

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In RA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In AA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, headache, acne, hyperlipidemia, creatine phosphokinase increase, urinary tract infection, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant is not recommended in patients with RA or AA and severe hepatic impairment or severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m^2).

Please see following pages for Brief Summary of Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis.

BA HCP ISI RA-AA 13JUN2022

References: 1. Olumiant. Prescribing Information. Lilly USA, LLC. **2.** King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *N Engl J Med.* 2022;386(18):1687-1699. **3.** King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *N Engl J Med.* 2022;386(suppl 1):1-77. **4.** Data on file. Lilly USA, LLC. DOF-BA-US-0075.

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PP-BA-US-1702 06/2022
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Lilly

OLUMIANT® (baricitinib) TABLETS BRIEF SUMMARY OF PRESCRIBING INFORMATION

Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE

Rheumatoid Arthritis: Olumiant is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.

Limitations of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

Coronavirus Disease 2019 (COVID-19): Olumiant is indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Alopecia Areata: Olumiant is indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

If a serious infection develops, interrupt Olumiant until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Patients, except those with COVID-19, should be tested for latent tuberculosis before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another JAK inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

THROMBOSIS

Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Patients with symptoms of thrombosis should discontinue Olumiant and be promptly evaluated.

WARNINGS AND PRECAUTIONS

Serious Infections—Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients with rheumatoid arthritis receiving Olumiant. The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis
- with a history of a serious or an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
- with underlying conditions that may predispose them to infection.

In patients with rheumatoid arthritis or alopecia areata, closely monitor for the development of signs and symptoms of infection during and after treatment with Olumiant. Interrupt Olumiant in patients with rheumatoid arthritis or alopecia areata, if the patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with Olumiant should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient; appropriate antimicrobial therapy should be initiated, the patient should be closely monitored, and Olumiant should be interrupted if the patient is not responding to therapy. Do not resume Olumiant until the infection is controlled.

In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with Olumiant. There is limited information regarding the use of Olumiant in patients with COVID-19 and concomitant active serious infections. The risks and benefits of treatment with Olumiant in COVID-19 patients with other concurrent infections should be considered.

Tuberculosis—Evaluate patients for active infection prior to administration of Olumiant. Olumiant should not be given to patients with active tuberculosis (TB).

Test patients with rheumatoid arthritis or alopecia areata for latent tuberculosis. Patients with rheumatoid arthritis or alopecia areata and latent TB should be treated with standard antimycobacterial therapy before initiating Olumiant. Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection. Consultation with a physician with expertise in the treatment of TB is recommended to aid in the decision about whether initiating anti-TB therapy is appropriate for an individual patient.

During Olumiant use, monitor patients for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy.

Viral Reactivation—Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves.

The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Patients with evidence of active hepatitis B or C infection were excluded from clinical trials. In clinical trials in patients with rheumatoid arthritis or alopecia areata, patients who were positive for hepatitis C antibody but negative for hepatitis C virus RNA were permitted to enroll. Patients with positive hepatitis B surface antibody and hepatitis B core antibody, without hepatitis B surface antigen, were permitted to enroll; such patients should be monitored for expression of hepatitis B virus (HBV) DNA. Should HBV DNA be detected, consult with a hepatologist. Perform screening for viral hepatitis in accordance with clinical guidelines before starting therapy with Olumiant.

Mortality—In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with the JAK inhibitor compared with TNF blockers. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

Malignancy and Lymphoproliferative Disorders— Malignancies were observed in clinical studies of Olumiant.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers. In this study, current or past smokers had an additional increased risk of overall malignancies.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

OLUMIANT® (baricitinib) BA HCP BS 13JUN2022

Non-melanoma skin cancers—NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Major Adverse Cardiovascular Events—In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke was observed with the JAK inhibitor compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Thrombosis—Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, arterial thrombosis events in the extremities have been reported in clinical studies with Olumiant. Many of these adverse events were serious and some resulted in death. There was no clear relationship between platelet count elevations and thrombotic events. In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of overall thrombosis, DVT, and PE were observed compared to those treated with TNF blockers.

If clinical features of DVT/PE or arterial thrombosis occur, patients should discontinue Olumiant and be evaluated promptly and treated appropriately. Avoid Olumiant in patients that may be at increased risk of thrombosis.

Hypersensitivity—Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

Gastrointestinal Perforations—Gastrointestinal perforations have been reported in clinical studies with Olumiant.

Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Evaluate promptly patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation.

Laboratory Abnormalities

Neutropenia—Treatment with Olumiant was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] less than 1000 cells/mm^3) compared to placebo.

In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with an ANC less than 1000 cells/mm^3.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with ANC less than 1000 cells/mm^3. Avoid initiation or interrupt Olumiant treatment in patients with COVID-19 and an ANC less than 500 cells/mm^3.

Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on ANC.

Lymphopenia—Absolute lymphocyte count (ALC) less than 500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo.

In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with an ALC less than 500 cells/mm^3.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with ALC less than 200 cells/mm^3. Avoid initiation or interrupt Olumiant treatment in patients with COVID-19 and an ALC less than 200 cells/mm^3.

Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on ALC.

Anemia—Decreases in hemoglobin levels to less than 8 g/dL were reported in Olumiant clinical trials. In patients with rheumatoid arthritis or alopecia areata, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin less than 8 g/dL. Evaluate at baseline and thereafter according to routine patient management. Adjust dosing based on hemoglobin levels.

In patients with COVID-19, there is limited information regarding use of Olumiant in patients with hemoglobin less than 8 g/dL.

Liver Enzyme Elevations—Treatment with Olumiant was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of ALT ≥5 times upper limit of normal (ULN) and increases of AST ≥10 times ULN were observed in patients in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations—Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Assessment of lipid parameters should be performed approximately 12 weeks following Olumiant initiation in patients with rheumatoid arthritis or alopecia areata. Manage patients according to clinical guidelines for the management of hyperlipidemia.

Vaccinations—Avoid use of live vaccines with Olumiant. Update immunizations in patients with rheumatoid arthritis or alopecia areata prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling *(see Warnings and Precautions)*: Serious Infections; Mortality; Malignancy and Lymphoproliferative Disorders; Major Adverse Cardiovascular Events; Thrombosis; Hypersensitivity; Gastrointestinal Perforations; Laboratory Abnormalities.

Clinical Trials Experience—Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not predict the rates observed in a broader patient population in clinical practice.

Adverse Reactions in Patients with Rheumatoid Arthritis—The safety of Olumiant was evaluated in six randomized, double-blind, placebo-controlled studies (three Phase 2, three Phase 3) and a long-term extension study in patients with moderately to severely active RA. Patients were randomized to placebo (1070 patients), Olumiant 2 mg (479 patients), or baricitinib 4 mg (997 patients).

Patients could be switched to baricitinib 4 mg from placebo or Olumiant 2 mg from as early as Week 12 depending on the study design. All patients initially randomized to placebo were switched to baricitinib 4 mg by Week 24.

During the 16-week treatment period, adverse events leading to discontinuation of treatment were reported by 35 patients (11.4 per 100 patient-years) treated with placebo, 17 patients (12.1 per 100 patient-years) with Olumiant 2 mg, and 40 patients (13.4 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, adverse events leading to discontinuation of treatment were reported by 31 patients (9.2 per 100 patient-years) with Olumiant 2 mg, and 92 patients (10.2 per 100 patient-years) treated with baricitinib 4 mg.

Overall Infections—During the 16-week treatment period, infections were reported by 253 patients (82.1 per 100 patient-years) treated with placebo, 139 patients (99.1 per 100 patient-years) treated with Olumiant 2 mg, and 298 patients (100.1 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, infections were reported by 200 patients (59.6 per 100 patients-years) treated with Olumiant 2 mg, and 500 patients (55.3 per 100 patient-years) treated with baricitinib 4 mg.

In the 0 to 52-week exposure population, the most commonly reported infections with Olumiant were viral upper respiratory tract infection, upper respiratory tract infection, urinary tract infection, and bronchitis.

Serious Infections—During the 16-week treatment period, serious infections were reported in 13 patients (4.2 per 100 patient-years) treated with placebo, 5 patients (3.6 per 100 patient-years) treated with Olumiant 2 mg, and 11 patients (3.7 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, serious infections were reported in 14 patients (4.2 per 100 patient-years) treated with Olumiant 2 mg and 32 patients (3.5 per 100 patient-years) treated with baricitinib 4 mg.

In the 0 to 52 week exposure population, the most commonly reported serious infections with Olumiant were pneumonia, herpes zoster, and urinary tract infection.

Tuberculosis—During the 16-week treatment period, no events of tuberculosis were reported.

During 0 to 52-week exposure, events of tuberculosis were reported in 0 patients treated with Olumiant 2 mg and 1 patient (0.1 per 100 patient-years) treated with baricitinib 4 mg.

Cases of disseminated tuberculosis were also reported.

Opportunistic Infections (excluding tuberculosis)—During the 16-week treatment period, opportunistic infections were reported in 2 patients (0.6 per 100 patient-years) treated with placebo, 0 patients treated with Olumiant 2 mg and 2 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg.

During 0 to 52-week exposure, opportunistic infections were reported in 1 patient (0.3 per 100 patient-years) treated with Olumiant 2 mg and 5 patients (0.6 per 100 patient-years) treated with baricitinib 4 mg.

Malignancies—During the 16-week treatment period, malignancies excluding non-melanoma skin cancers (NMSC) were reported in 0 patients treated with placebo, 1 patient (0.7 per 100 patient-years) treated with Olumiant 2 mg, and 1 patient (0.3 per 100 patient-years) treated with baricitinib 4 mg.

During the 0 to 52-week treatment period, malignancies excluding NMSC were reported in 2 patients (0.6 per 100 patient-years) treated with Olumiant 2 mg and 6 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg.

Thrombosis

Venous Thrombosis—During the 16-week treatment period, venous thromboses (deep vein thrombosis or pulmonary embolism) were reported in 0 patients treated with placebo, 0 patients treated with Olumiant 2 mg, and 5 patients (1.7 per 100 patient-years) treated with baricitinib 4 mg. During the 0 to 52-week treatment period, venous thromboses were reported in 2 patients (0.6 per 100 patient-years) treated with Olumiant 2 mg and 7 patients (0.8 per 100 patient-years) treated with baricitinib 4 mg.

Arterial Thrombosis—During the 16-week treatment period, arterial thromboses were reported in 1 patient treated with placebo (0.3 per 100 patient-years), 2 patients (1.4 per 100 patient-years) treated with Olumiant 2 mg, and 2 patients (0.7 per 100 patient-years) treated with baricitinib 4 mg. During the 0 to 52-week treatment period, arterial thromboses were reported in 3 patients (0.9 per 100 patient-years) treated with Olumiant 2 mg and 3 patients (0.3 per 100 patient-years) treated with baricitinib 4 mg.

Laboratory Abnormalities

Neutropenia—During the 16-week treatment period, neutrophil counts below 1000 cells/mm^3 occurred in 0% of patients treated with placebo, 0.6% of patients treated with Olumiant 2 mg, and 0.3% of patients treated with baricitinib 4 mg. There were no neutrophil counts below 500 cells/mm^3 observed in any treatment group.

Platelet Elevations—During the 16-week treatment period, increases in platelet counts above 600,000 cells/mm^3 occurred in 1.1% of patients treated with placebo, 1.1% of patients treated with Olumiant 2 mg, and 2.0% of patients treated with baricitinib 4 mg. Mean platelet count increased by 3000 cells/mm^3 at 16 weeks in patients treated with placebo, by 15,000 cells/mm^3 at 16 weeks in patients treated with Olumiant 2 mg and by 23,000 cells/mm^3 in patients treated with baricitinib 4 mg.

Liver Enzyme Elevations—Events of increases in liver enzymes ≥3 times the ULN were observed in patients treated with Olumiant.

- During the 16-week treatment period, ALT elevations ≥3 times the ULN occurred in 1.0% of patients treated with placebo, 1.7% of patients treated with Olumiant 2 mg, and 1.4% of patients treated with baricitinib 4 mg.
- During the 16-week treatment period, AST elevations ≥3 times the ULN occurred in 0.8% of patients treated with placebo, 1.3% of patients treated with Olumiant 2 mg, and 0.8% of patients treated with baricitinib 4 mg.
- In a phase 3 study of DMARD naive patients, during the 24-week treatment period, ALT and AST elevations ≥3 times the ULN occurred in 1.9% and 0% of patients treated with methotrexate monotherapy, 1.9% and 1.3% of patients treated with baricitinib 4 mg monotherapy, and 4.7% and 1.9% of patients treated with baricitinib 4 mg plus methotrexate.

Lipid Elevations—In controlled clinical trials, Olumiant treatment was associated with dose-related increases in lipid parameters, including total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol. Elevations were observed at 12 weeks and remained stable thereafter. During the 12-week treatment period, changes in lipid parameters are summarized below:

- Mean LDL cholesterol increased by 8 mg/dL in patients treated with Olumiant 2 mg and by 14 mg/dL in patients treated with baricitinib 4 mg.
- Mean HDL cholesterol increased by 7 mg/dL in patients treated with Olumiant 2 mg and by 9 mg/dL in patients treated with baricitinib 4 mg.
- The mean LDL/HDL ratio remained stable.
- Mean triglycerides increased by 7 mg/dL in patients treated with Olumiant 2 mg and by 15 mg/dL in patients treated with baricitinib 4mg.

Creatine Phosphokinase (CPK)—Olumiant treatment was associated with increases in CPK within one week of starting Olumiant and plateauing after 8 to 12 weeks. At 16 weeks, the mean change in CPK for Olumiant 2 mg and baricitinib 4 mg was 37 IU/L and 52 IU/L, respectively.

Creatinine—In controlled clinical trials, dose-related increases in serum creatinine were observed with Olumiant treatment. At 52 weeks, the mean increase in serum creatinine was less than 0.1 mg/dL with baricitinib 4 mg. The clinical significance of the observed serum creatinine increases is unknown.

Other Adverse Reactions—Other adverse reactions are summarized in the following table.

Adverse Reactions Occurring in Greater Than or Equal to 1% of Olumiant 2 mg and Baricitinib 4 mg Treated Patients in Placebo-Controlled Trials for Rheumatoid Arthritis

	Weeks 0-16		
	Placebo n=1070 (%)	Olumiant 2 mg n=479 (%)	Baricitinib 4 mg n=997 (%)
Upper respiratory tract infections[a]	11.7	16.3	14.7
Nausea	1.6	2.7	2.8
Herpes simplex[b]	0.7	0.8	1.8
Herpes zoster	0.4	1.0	1.4

[a] Includes acute sinusitis, acute tonsillitis, chronic tonsillitis, epiglottitis, laryngitis, nasopharyngitis, oropharyngeal pain, pharyngitis, pharyngotonsillitis, rhinitis, sinobronchitis, sinusitis, tonsillitis, tracheitis, and upper respiratory tract infection.

[b] Includes eczema herpeticum, genital herpes, herpes simplex, ophthalmic herpes simplex, and oral herpes.

Additional adverse drug reactions occurring in fewer than 1% of patients: acne.

Adverse Reactions in Patients with COVID-19—The safety of Olumiant was evaluated in two randomized, double-blind, placebo-controlled clinical trials of hospitalized adults with COVID-19 for up to 29 days, in which 1307 patients received at least one dose of Olumiant 4 mg once daily, and 1310 patients received placebo, for up to 14 days or until hospital discharge, whichever occurred first. In these studies, prophylaxis for venous thromboembolic event (VTEs) was recommended or required for all patients unless a major contraindication was noted.

Overall, the safety profile observed in patients with COVID-19 treated with Olumiant was consistent with the safety profile in patients with rheumatoid arthritis.

Overall Infections—During the first 29 days of the randomized clinical trials, infections were reported in 194 patients (14.8%) treated with Olumiant 4 mg and by 219 patients (16.7%) treated with placebo. The most commonly reported infection with Olumiant was pneumonia (3.1%).

Serious Infections—During the first 29 days of the randomized clinical trials, serious infections were reported in 98 patients (7.5%) treated with Olumiant 4 mg and 120 patients (9.2%) treated with placebo. The most commonly reported serious infections with Olumiant were COVID-19 pneumonia (2.1%) and septic shock (2.1%).

Opportunistic Infections—During the first 29 days of the randomized clinical trials, opportunistic infections were reported in 12 patients (0.9%) treated with Olumiant 4 mg and 14 patients (1.1%) treated with placebo. Tuberculosis was reported in 1 patient (0.1%) treated with Olumiant 4 mg and 0 patients treated with placebo.

Venous Thrombosis Events—During the first 29 days of the randomized clinical trials, pulmonary embolism was reported in 20 patients (1.5%) treated with Olumiant 4 mg and 11 patients (0.8%) treated with placebo. Deep vein thrombosis was reported in 20 patients (1.5%) treated with Olumiant 4 mg and 18 patients (1.4%) treated with placebo.

Adverse drug reactions in greater than or equal to 1% of patients in trials for COVID-19 are summarized in the following table.

Adverse Reactions That Occurred in Greater Than or Equal to 1% of Patients Treated with Olumiant 4 mg During the First 29 Days in Placebo-Controlled Trials for COVID-19

	Placebo N=1310 n (%)	Olumiant 4 mg N=1307 n (%)
ALT ≥3 x ULN[a]	201(16.0)	230 (18.1)
AST ≥3 x ULN[a]	117 (9.4)	149 (11.8)
Thrombocytosis >600,000 cells/mm^3[a]	34 (4.6)	59 (7.9)
Creatine phosphokinase (CPK) >5 x ULN[a, b]	38 (4.7)	36 (4.5)
Neutropenia <1000 cells/mm^3[a]	22 (1.8)	26 (2.2)
Deep vein thrombosis	18 (1.4)	20 (1.5)
Pulmonary embolism	11 (0.8)	20 (1.5)
Urinary tract infection	13 (1.0)	19 (1.5)

[a] As assessed by measured values within the clinical trial database. Frequencies are based on shifts from pre-treatment to post-treatment (with number at risk as the denominator), except for ALT and AST for which frequencies are based on observed elevation during treatment.

[b] Creatine phosphokinase frequencies presented in the table were available for a single trial (COVID II) in patients with COVID-19 and do not represent integrated data.

Adverse Reactions in Patients with Alopecia Areata—The safety of Olumiant was evaluated in two placebo-controlled studies in patients with severe alopecia areata (one phase 2/3 study, and one phase 3 study). Patients were randomized to placebo (371 patients), Olumiant 2 mg (365 patients), or Olumiant 4 mg (540 patients). Of these, a total of 845 patients were treated with Olumiant for at least 1 year.

The following table summarizes adverse reactions that occurred at a frequency of at least 1% in patients treated with Olumiant 2 mg once daily or Olumiant 4 mg once daily and more frequently than in patients treated with placebo during the 36-week placebo-controlled period of the alopecia areata clinical trials.

Adverse Reactions That Occurred in ≥1% of Patients Treated with Olumiant 2 mg or Olumiant 4 mg in Alopecia Areata Trials

	Weeks 0-36		
	Placebo n=371 (%)[a]	Olumiant 2 mg n=365 (%)[a]	Olumiant 4 mg n=540 (%)[a]
Upper respiratory tract infections (URTI)[b]	19.9	18.4	21.3
Headache	5.4	5.5	6.6
Acne[c]	2.2	5.8	5.9
Hyperlipidemia[d]	3.0	3.6	5.9
Blood creatine phosphokinase increased	1.3	0.8	4.3
Urinary tract infections (UTI)[e]	2.2	3.8	3.7

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Adverse Reactions That Occurred in ≥1% of Patients Treated with Olumiant 2 mg or Olumiant 4 mg in Alopecia Areata Trials (Cont.)

	Weeks 0-36		
	Placebo n=371 (%)[a]	Olumiant 2 mg n=365 (%)[a]	Olumiant 4 mg n=540 (%)[a]
Liver enzyme elevations[f]	2.4	1.1	3.0
Folliculitis[g]	0.8	1.4	2.2
Fatigue	1.1	0.8	2.2
Lower respiratory tract infections (LRTI)[h]	0.8	2.2	2.0
Nausea	1.6	2.7	2.0
Genital Candida infections[i]	0.3	2.2	1.3
Anemia	0.3	0.3	1.3
Neutropenia[j]	0.8	0.3	1.3
Abdominal pain[k]	2.2	3.8	0.9
Herpes zoster	0.5	1.4	0.9
Weight increased	0.3	1.6	0.9

[a] %-study size adjusted percentages.

[b] URTI includes: acute sinusitis, influenza, laryngitis, nasopharyngitis, oropharyngeal pain, pharyngitis, pharyngotonsillitis, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, viral upper respiratory tract infection, viral sinusitis, viral pharyngitis, respiratory tract infection viral, rhinovirus infection and adenoiditis

[c] Acne includes: acne and dermatitis acneiform.

[d] Hyperlipidemia includes: hyperlipidaemia, hypercholesterolaemia, hypertriglyceridaemia, dyslipidaemia, lipids increased, low density lipoprotein increased, blood cholesterol increased, and blood triglycerides increased.

[e] UTI includes: cystitis, urinary tract infection, white blood cells urine positive, urinary tract infection bacterial, and pyelonephritis.

[f] Liver enzyme elevations includes: transaminases increased, aspartate aminotransferase increased, alanine aminotransferase increased, hepatic enzyme increased, gamma-glutamyl transferase increased, and hepatic function abnormal.

[g] Folliculitis was most commonly localized in the scalp region associated with hair regrowth.

[h] LRTI includes: bronchitis, bronchiolitis, lower respiratory tract infection, pneumonia, COVID-19 pneumonia, and respiratory tract infection.

[i] Genital Candida infections includes: vulvovaginal candidiasis, vulvovaginal mycotic infection, and genital infection fungal.

[j] Neutropenia includes: neutropenia and neutrophil count decreased.

[k] Abdominal pain includes: abdominal pain, abdominal pain lower, abdominal pain upper, and abdominal discomfort.

In patients treated with any dose of baricitinib, adverse reactions that occurred in fewer than 1% of patients include arterial thrombosis, B cell lymphoma, lymphopenia, and fungal skin infections.

Additional adverse reactions observed after Week 52: venous thromboembolic events (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), and malignancy including non-melanoma skin cancer.

Overall, the adverse reactions observed in patients with alopecia areata treated with Olumiant were consistent with the adverse reactions in patients with rheumatoid arthritis.

Postmarketing Experience—The following adverse reactions have been identified during post-approval use of Olumiant. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Drug hypersensitivity (events such as rash, urticaria, and angioedema have been observed).

DRUG INTERACTIONS

Strong OAT3 Inhibitors—Baricitinib exposure is increased when Olumiant is co-administered with strong Organic Anion Transporter 3 (OAT3) inhibitors (such as probenecid), hence the dosage of baricitinib should be reduced by half the recommended dose.

Other JAK Inhibitors or Biologic DMARDs—Olumiant has not been studied in combination with other JAK inhibitors or with biologic DMARDs.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary—Based on the findings from animal reproduction studies, Olumiant may cause fetal harm during pregnancy. Available data from clinical trials and postmarketing case reports with Olumiant exposure in pregnancy are insufficient to inform a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are no human data on chronic baricitinib exposure throughout pregnancy. There are risks to the mother and the fetus associated with rheumatoid arthritis in pregnancy. Consider the risks and benefits with chronic use of Olumiant during pregnancy.

In animal embryo-fetal development studies, oral baricitinib administration to pregnant rats and rabbits at exposures equal to and greater than approximately 11 and 46 times the maximum recommended human dose (MRHD) of 4 mg/day, respectively, resulted in reduced fetal body weights, increased embryolethality (rabbits only), and dose-related increases in skeletal malformations. No developmental toxicity was observed in pregnant rats and rabbits treated with oral baricitinib during organogenesis at approximately 2 and 7 times the exposure at the MRHD, respectively. In a pre- and post-natal development study in pregnant female rats, oral baricitinib administration at exposures approximately 24 times the MRHD resulted in reduction in pup viability (increased incidence of stillborn pups and early neonatal deaths), decreased fetal birth weight, reduced fetal body weight gain, decreased cytotoxic T cells on post-natal day (PND) 35 with evidence of recovery by PND 65, and developmental delays that might be attributable to decreased body weight gain. No developmental toxicity was observed at an exposure approximately 5 times the exposure at the MRHD.

The background risks of major birth defects and miscarriage for the indicated population(s) are 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 2-4% and 15-20%, respectively.

Report pregnancies to Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Clinical Considerations—*Disease-Associated Maternal and/or Embryo/Fetal Risk:* Published data suggest that increased disease activity is associated with the risk of developing adverse pregnancy outcomes in women with rheumatoid arthritis. Adverse pregnancy outcomes include preterm delivery (before 37 weeks of gestation), low birth weight (less than 2500 g) infants, and small for gestational age at birth.

Data—*Animal Data:* In an embryofetal development study in pregnant rats, dosed orally during the period of organogenesis from gestation days 6 to 17, baricitinib was teratogenic (skeletal malformations that consisted of bent limb bones and rib anomalies) at exposures equal to or greater than approximately 11 times the MRHD (on an AUC basis at maternal oral doses of 10 mg/kg/day and higher). No developmental toxicity was observed in rats at an exposure approximately 2 times the MRHD (on an AUC basis at a maternal oral dose of 2 mg/kg/day).

In an embryofetal development study in pregnant rabbits, dosed orally during the period of organogenesis from gestation days 7 to 20, embryolethality, decreased fetal body weights, and skeletal malformations (rib anomalies) were observed in the presence of maternal toxicity at an exposure approximately 46 times the MRHD (on an AUC basis at a maternal oral dose of 30 mg/kg/day). Embryolethality consisted of increased post-implantation loss that was due to elevated incidences of both early and late resorptions. No developmental toxicity was observed in rabbits at an exposure approximately 7 times the MRHD (on an AUC basis at a maternal oral dose of 10 mg/kg/day).

In a pre- and post-natal development study in pregnant female rats dosed orally from gestation day 6 through lactation day 20, adverse findings observed in pups included decreased survival from birth to post-natal day 4 (due to increased stillbirths and early neonatal deaths), decreased birth weight, decreased body weight gain during the pre-weaning phase, increased incidence of malrotated forelimbs during the pre-weaning phase, and decreased cytotoxic T cells on PND 35 with recovery by PND 65 at exposures approximately 24 times the MRHD (on an AUC basis at a maternal oral dose of 25 mg/kg/day). Developmental delays (that may be secondary to decreased body weight gain) were observed in males and females at exposures approximately 24 times the MRHD (on an AUC basis at a maternal oral dose of 25 mg/kg/day). These findings included decreased forelimb and hindlimb grip strengths, and delayed mean age of sexual maturity. No developmental toxicity was observed in rats at an exposure approximately 5 times the MRHD (on an AUC basis at a maternal oral dose of 5 mg/kg/day).

Lactation

Risk Summary—No information is available on the presence of Olumiant in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Baricitinib is present in the milk of lactating rats. Because of the potential for serious adverse reactions in nursing infants advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose (approximately 5 to 6 half-lives).

Data—A single oral dose of 25 mg/kg radiolabeled baricitinib was administered to lactating female Sprague-Dawley rats on post-partum day 13. Drug exposure was approximately 45-fold greater in milk than in plasma based on AUC_{0-t} values.

Females and Males of Reproductive Potential

Contraception—Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Consider pregnancy planning and prevention for females of reproductive potential.

Pediatric Use—The safety and effectiveness of Olumiant in pediatric patients have not been established.

Geriatric Use—Of the 3100 patients treated in the rheumatoid arthritis clinical trials, a total of 537 patients were 65 years of age and older, including 71 patients 75 years of age and older. Of the 2558 patients treated in the COVID-19 clinical trials, a total of 791 were 65 years of age and older, including 295 patients 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects,

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and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Of the 1200 patients in the alopecia areata trials, a total of 29 patients were 65 years of age or older. The number of patients aged 65 years and older was not sufficient to determine whether they respond differently from younger patients.

Olumiant is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because geriatric patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Hepatic Impairment—No dose adjustment is necessary in patients with mild or moderate hepatic impairment.

The use of Olumiant has not been studied in patients with rheumatoid arthritis or alopecia areata and severe hepatic impairment and is therefore not recommended. Olumiant has not been studied in patients with COVID-19 and severe hepatic impairment. Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk.

Renal Impairment—Renal function was found to significantly affect baricitinib exposure.

Rheumatoid Arthritis and Alopecia Areata**—**The recommended dosage of Olumiant in patients with moderate renal impairment (estimated glomerular filtration rate [GFR] between 30 and <60 mL/min/1.73 m^2) should be reduced by half the recommended dose. Olumiant is not recommended for use in patients with rheumatoid arthritis or alopecia areata and severe renal impairment (estimated GFR of less than 30 mL/min/1.73 m^2).

COVID-19**—**The recommended dosage of Olumiant in patients with moderate renal impairment (estimated GFR between 30 and <60 mL/min/1.73 m^2) or severe renal impairment (estimated GFR between 15 and <30 mL/min/1.73 m^2) is 2 mg once daily and 1 mg once daily, respectively. Olumiant is not recommended for use in patients who are on dialysis, have end-stage renal disease (ESRD), or with estimated GFR of <15 mL/min/1.73 m^2.

OVERDOSAGE

Single doses up to 40 mg and multiple doses of up to 20 mg daily for 10 days have been administered in clinical trials without dose-limiting toxicity. Pharmacokinetic data of a single dose of 40 mg in healthy volunteers indicate that more than 90% of the administered dose is expected to be eliminated within 24 hours.

In case of an overdose, it is recommended that the patient should be monitored for signs and symptoms of adverse reactions. Patients who develop adverse reactions should receive appropriate treatment.

Additional information can be found at www.Olumiant.com

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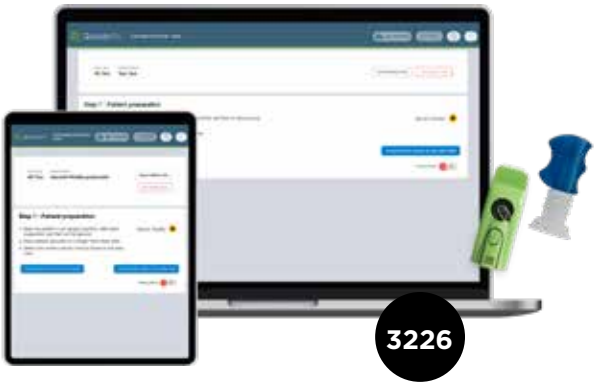
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1. Howell, S. C., & Master, R. C. (2023). Clinical Evaluation of Volume Plethysmography as an Aid for Diagnosis of Heart Failure in the Primary Care Setting. Journal of Preventive Medicine, 8(2). https://doi.org/https://preventive-medicine.imedpub.com/clinical-evaluation-of-volume-plethysmography-as-an-aid-for-diagnosis-of-heart-failure-in-the-primary-care-setting.pdf

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BY BRANDI BROWER

The name for Japan derives from the Japanese word Nihon, which means "sun origin" or "land of the rising sun," reflecting its position in eastern Asia. The sun has not set on my adventures in this intriguing country; it has just begun. The sun is still high in the sky as my Shinkansen train slows to a stop at the famous Tokyo Station. The prominent red brick edifice, constructed in 1914, is the busiest in Japan, with over 4,000 trains arriving and departing, ushering 1.1 million people using the station daily.

Japanese proverb: *Koketsu ni irazunba koji-o ezu*

Translation: If you do not enter the tiger's cave, you will not catch its cub.

Meaning: Nothing ventured, nothing gained. The train station's size, the language barrier, and the immensity of the famous city itself (data determined that Tokyo has a total land area greater and is more populated than New York City.) I feel intimidated as I make my way out to the street in the heart of the Marunouchi business district with its towering skyscrapers; this is my proverbial tiger's cave. But I'm determined to brave this new world and catch the cub.

In the Japanese culture, proverbs play an essential role, passed down through generations, touching upon almost every aspect of life. It's not just about knowing the words and their meanings; it serves as a window into the ethics and beliefs of what people value most. As I navigate my experiences in this fascinating country, I will lean into some of these proverbs and the bits of wisdom they offer.

Marunouchi District is the center of the business district of Tokyo, situated between the Imperial Palace and Tokyo Station. Marunouchi means "inside the circle," which refers to its location within the palace's outer moat. Nestled discreetly inside the heart of this bustling enterprise arena, Four Seasons Hotel Tokyo at Marunouchi. A five-minute walk, passing Memory Lane or Yakitori Alley, where white-collar "salarymen" drop down from their high-rise towers for the small stalled eateries selling grilled meats and cold beer after work. It's a vibe with the chug, chug, clang, clang of the trains approaching/departing, the smell of yummy yakotori meat cooking, and later at night, the glow from the lanterns hanging outside the small establishments. Hidden off the busy main thoroughfare is the entrance to the Hotel. The doorman introduced me to the staff inside, who checked me in at the lovely but unassuming ground floor lobby, with high ceilings and attractive wood treatments on the walls, and showed me to the elevator.

The Hotel is on the lower floors of a 32-story glass tower, an intimate boutique hotel with just 57 rooms. This hidden gem is the perfect home base to tour all that Tokyo offers. Because of the small number of accommodations, it feels like you have the whole place to yourself, and the superior staff is there at your beck and call. Be prepared to say this phrase often: "Arigato gozaimasu." (Thank you very much.) I'm taken to my deluxe, premier room, a spacious space with clean contemporary style decor, lacquered doors and furniture, a sitting area and desk,





and a soft leather-covered headboard that reaches to the top of the wall, stretching out over the bed like a canopy, an attractive add. Signature Four Seasons beds with lux linens, bathroom features a large walk-in shower and separate soaking tub. A great focal point of the corner room is the floor-to-ceiling windows on two sides overlooking the courtyard below, neighboring glass towers above, and the trains weaving around the bend. With the proximity to Tokyo station, I thought the numerous trains would be a noisy nuisance (thanks to the triple-glazed windows, there was minimal sound). Still, I found the energy of it to be a fascinating distraction, mesmerized by the intricate dance of precision transportation running seamlessly. When it's time to shut out the glimmering lights of the cityscape, I touch the button by my bedside, and the window treatments and blackout blinds are magically drawn as I drift off to sleep.

I wake up late and hurry to the restaurant, craving avocado toast. Realizing I missed the breakfast cut-off, I walk back toward the elevator. A team member stopped me and said he'd be happy to seat me and have the kitchen prepare me some breakfast bites, a small but memorable gesture. The Four Seasons brand is known for its exceptional attention to detail and treatment of guests. But there's an additional factor at play here in Japan. The mindset of the Japanese people when it comes to hospitality. A deep-rooted culture derives from the sado tea ceremony called omotenashi, meaning to look after guests



wholeheartedly. That self-assured service within the walls of the Hotel is a microcosm of the country itself. Omotenashi is more than an attitude that the customer is always right; it is the understanding that every action is essential, even the smallest gesture if it ensures a great guest experience.

An example of omotenashi is when I ventured out of the Hotel to the famous "dish district." Even the mundane transaction of collecting currency or credit cards and placing the money on a small brass tray seems like a ritual of dignity, as the funds are gathered with grace and humility for the service rendered. It was a shop on Kappabashi Street, where the owner carefully wrapped my Tetsubin cast iron teapot in white tissue paper and placed it in a box as if it would be my most prized possession. How the shop owner's hand movements flow, the daily decorum of beauty, the way they find loveliness in the lowliest things - it impressed me to transform every day into moments of discovery and a desire to find beauty everywhere.

Four Seasons Hotel Tokyo at Marunouchi has bragging rights as host to one of Asia's top awarding-winning restaurants. Dine over dynamic French cuisine at the two-Michelin-starred culinary hot spot, SÉZANNE.

The accolades for 2023 include Best Restaurant in Japan, #2 on Asia's 50 Best Restaurants, and #37 on The World's 50 Best Restaurants lists.

With a relaxed luxury ambiance and a windowed show kitchen, guests can engage and enjoy watching Executive Chef Daniel Calvert curate plated precision and mouthwatering magic. What is the key to such success? "Consistency is the key, says Calvert, "Anyone can do something great once. Success lies in doing the same things over and over again, striving for excellence on every plate."

For any time of day fare, MAISON MARUNOUCHI is a Parisian-style restaurant with Western and Japanese breakfast, French bistro classics, and all-time favorites for lunch and dinner. Signature dishes to note: Merguez sausage, Tabbouleh with mint yogurt or whole roasted organic chicken, Ratatouille, and Soft Polenta. Not to be missed, Afternoon Tea at MAISON MARUNOUCHI. One of the highlights of my stay, thanks to the Pâtisserie perfection of Swiss transplant Executive Pastry Chef Patrick Thibaud. With 17 years of experience in haute pastry, Chef Thibaud's approach is centered around "the architecture of taste" – keeping the palate engaged with multiple flavors and textures that marry memorably with each bite. He finds the entire process of bringing a new idea to life deeply satisfying- during my visit, his inspiration was the flowers from his native Switzerland. While seated on the rounded white upholstered couch, the first segment of the two-hour service began as the starter was presented onto the light gray leather table top. The tea and beverages were fine, but the guests reserved seats for the Instagram-worthy savory and sweet edible art display. I observed the few patrons at intimate tables around me, dressed to impress, enjoying each delectable bite only after taking several photos of each petite pastry: Lavender and Apricot Macaron, Orange Flower Financier, Violet and Raspberry Cheesecake, Chamomile and Lemon Honey Choux to name a few. I admit to taking pictures of the colorful creations before slowly savoring their sweetness.

From sweetness to secluded quiet, I make my way on foot to the Imperial Palace grounds, home to the Emperor of Japan. Surrounded by thick walls, wide moats, and meticulously kept

gardens, it's an oasis of green in the center of a cement jungle. In the city, you can feel the vibrancy of the people, but once you're on the Imperial Palace grounds, you can absorb the natural beauty and the quiet calm.

Japanese Proverb: *Kachou Fuugetsu*

Translation: Flower, Bird, Wind, Moon

Meaning: Learn about yourself through experiencing the beauties of nature. The proverb refers to seeing the beauty in each season surrounding you and understanding that those things, and each of us, are beautiful at different times of the year and in different ways. "Flower, Bird, Wind, Moon" means the bright moon we see in Winter is no less beautiful than the moon in Summer; the wind we feel in Spring is different than the breeze through the trees in Autumn. We find ourselves and our happiness in nature -if we are open to it. Being in Japan, I have adopted the culture's deep appreciation for the miraculous changes in the seasons and how everything in nature, the good and the bad, is perfect and must be respected.

A spa day is always a good day—first, in-room breakfast service. Next, get the blood flowing in the fully equipped fitness center, then let the relaxation begin. With full use of the spa facilities before my treatment, I spend time in the ofuro bath and steam room in preparation for being pampered. My selected self splurge, the latest in rejuvenating facial treatments - Dermadrop TDA. I'm confident in the results of German technology combined with the meticulous skill of onsite practitioner Ms. Takahashi. A non-invasive micro-dermabrasion with supercharged ingredients to suit my needs, she suggests the Mitocell cartridge for my fine lines and wrinkles. I put my trust in the expert and the happy results: When FaceTiming my husband that evening, he took notice, said I was "glowing," and asked what I had done that day. A spa day is always a good day.

Japan's culture respects nature, and that sentiment is echoed in their kindness and respect for their fellow man.

Japanese Proverb: *Uogokoroarebamizugokoroari*

Translation: If a fish is kind to water, the water will be kind to fish.

Meaning: If someone shows kindness, their kindness will be returned- an excellent reminder to show respect to others. There is very little crime in the country compared to other places worldwide. Japan has one of the lowest homicide and robbery rates; walking in Tokyo any time of day or night, I felt completely safe. One would guess a contributing factor to low crime is pure respect for one another. Not only is it a safe country, but it is spotless. A metropolis the size of Tokyo, and there is no trash in sight. During my entire visit to the country, I did not spy a can or bottle on the sidewalk or a stray piece of paper blowing in the wind. I learned, for example, that if someone eats/drinks something from a vending machine, there are no trash cans on the streets because taking the trash with them to their homes is customary. Again, respect for their surroundings and kindness toward one another- a goal worth striving for.



To highlight the kindness of this country, I'll offer a tender experience. My contact at the Four Seasons Hotel Tokyo at Marunouchi is Ms. Otake. On my last day at the Hotel, she met up with me and asked if I had slept well the night before. My eyes welled up as I overshared how my mother had recently passed, and I couldn't sleep because I was missing her. As my tears crossed the barrier of my eyes and streamed down my face, Ms. Otake felt compassion for me and relayed her recent loss of her grandfather. She explained that Buddhist people try not to cry for their lost loved ones in fear their tears will rain upon them. Instead, we must try to be happy and smile so that the sun will continue to shine on them - a comforting thought.

The concept of "omoiyari" is of high value to the Japanese people.

There is no equivalent word in the English language for it.
Omoi means thought.

Yari is derived from yaru, which means give or send.
So omoiyari means to give your thoughts to others.
Much like sympathy or empathy, this concept helps people understand the joys and pain others feel so everyone can live harmoniously. Ms. Otake felt compassion for my loss, but as I prepared to leave the unique urban property, she handed me a bag from the gift shop and said it was something to hold onto whenever I missed my mother. Inside the Four Seasons tote, a teddy bear dressed in a kimono. It was a considerate and kind offering that touched my heart.

As I entered the taxi and waved goodbye to the genuine, smiling faces of the Four Seasons associates, a rush of gratitude washed over me.

Japanese proverb: *sumeba miyako*

Translation: If you live (there), it's the capital or the best place to be.

Meaning: Wherever you live, you come to love it. It becomes the most essential place in the world- home is where you make it. I can see why people are drawn to this country, why so many love to visit again and again, and why so many others call this extraordinary place, the land of the rising sun, "home."



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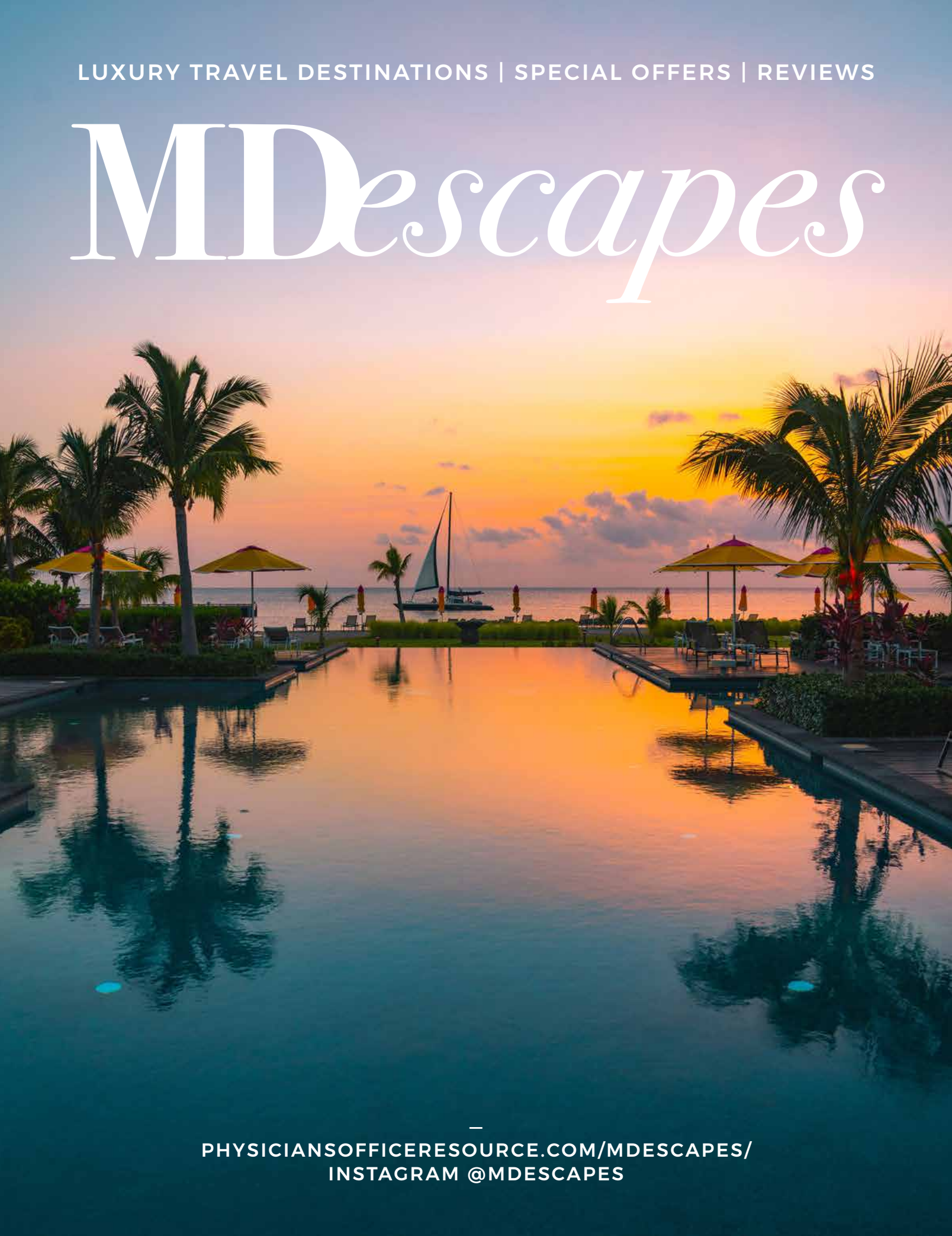
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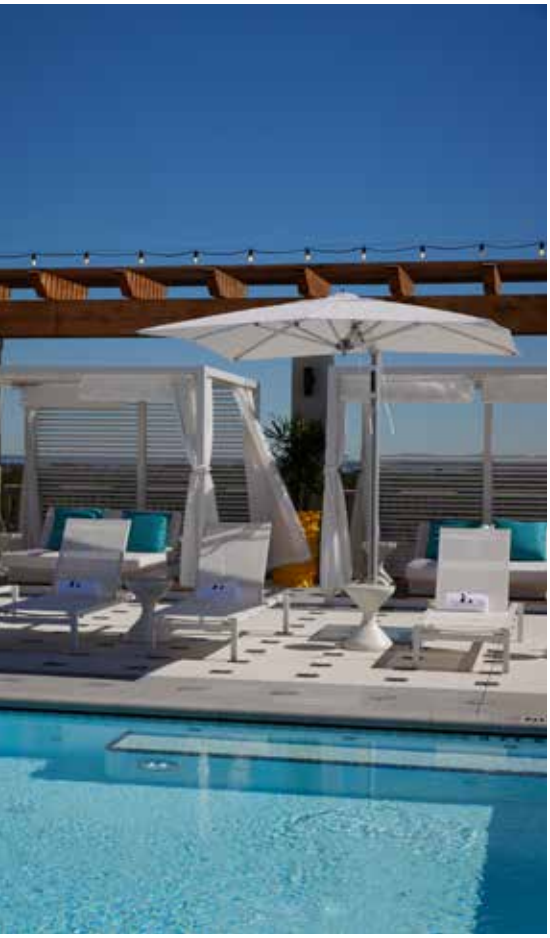
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