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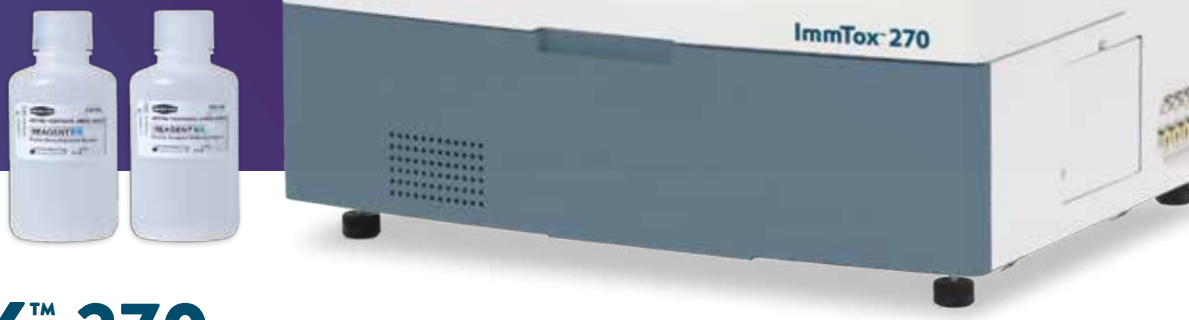
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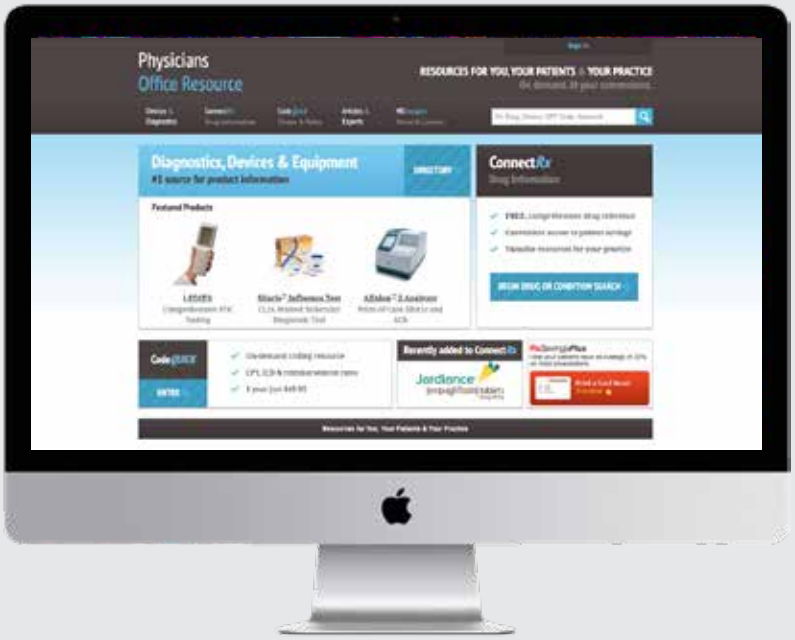
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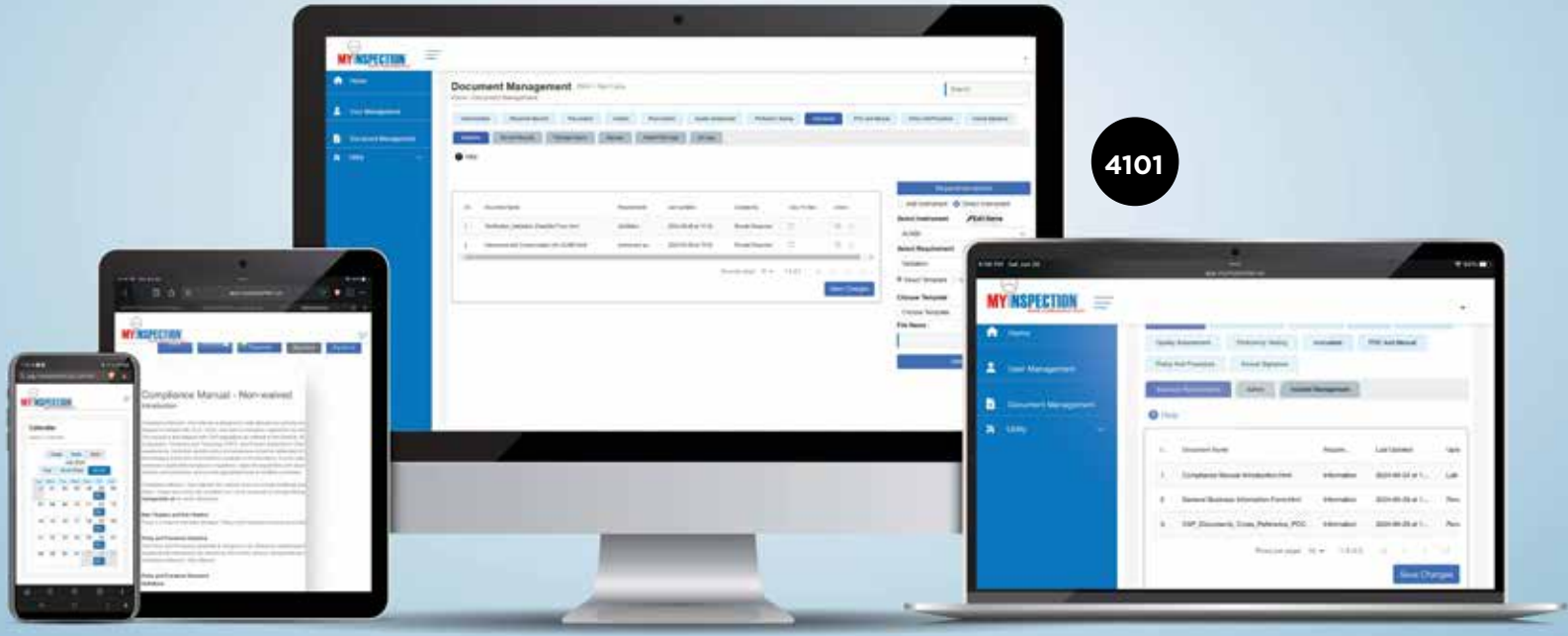
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How to Create a Medical Empire Part 3: Creating a Multispecialty Group

This chapter is aimed at the physician investor/ entrepreneur as they navigate their path into the expansive realm of medical careers and opportunities.

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PART 3 OF A 6 PART SERIES

HOW TO CREATE A MEDICAL EMPIRE PART 3: Creating a Multispecialty Group

BY DR. SHAKEEL AHMED

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"I can do things you cannot, you can do things I cannot; together we can do great things."

—MOTHER THERESA

This chapter is aimed at the physician investor/entrepreneur as they navigate their path into the expansive realm of medical careers and opportunities. Although opening a medical group might not be categorized strictly as an investment, this business choice will significantly shape the future of your financial returns and endeavors in the healthcare field. This is coupled with the occasional need to invest in these models, which sets the stage perfectly for an investment framework.

Physicians have a plethora of employment models to choose from, including single-specialty groups, multispecialty groups, solo practices, and hospital employment. For the sake of discussion, I will assume the reader is an existing physician looking to broaden his practice horizon: In comes the concept of expanding into a multi-specialty group. For those considering multispecialty groups, which often involve capital investment and promise subsequent returns, diligent research is essential.

First, a few words to describe these entities. Medical multispecialty groups are collaborative bodies that bring together healthcare providers from various specialties to deliver comprehensive care to patients. These groups typically include primary care physicians, specialists, nurses, nurse practitioners, and physician assistants. There are numerous compelling reasons for such structured practices to exist. Some reasons are obvious, while others may not be immediately apparent. There are also other factors to consider before diving into this venture, as it involves significant complexities and the interplay of many personalities can result in either harmonious or contentious outcomes. Nevertheless, there is strength in numbers, and when a group of physicians unites their economic objectives, shared operational costs, and collective bargaining power, a multispecialty group can thrive remarkably.

"The whole is greater than the sum of its parts."
—Aristotle

According to the Medical Group Management Association (MGMA), in 2021, there were approximately forty-five thousand medical groups in the US, about 75 percent of which were multispecialty groups. This prevalence indicates substantial underlying benefits.

As the landscape of medicine transforms from year to year and law to law, the advantage has tended to favor the multispecialty group setup. However, some supposedly level playing fields are less neutral than others. But this is already known.

"The Roman arena was technically a level playing field. On one side were the lions, fully equipped, and on the other, the Christians, marked for slaughter. That's not a level playing field; that's a predetermined defeat."
—Louis O. Kelso.

The dynamic nature of medical practice structures and politics mandates that individual practitioners continuously position themselves advantageously. This need has spurred the development of medical multispecialty groups, which, when effectively orchestrated, can provide both fairness and favorable conditions.

While some multispecialty groups are shaped from the scars of battle, most are also systematically built from the ground up to align common goals and mitigate various risks. Where you fit in this structure depends on whether you are a founding member, have earned your way into ownership, or are looking to buy in de novo.

Key Considerations in Establishing a Multispecialty Medical Group

1- Overhead Costs:

Deciding between a simple coverage arrangement, a partnership, or various positions within a partnership can present daunting choices. Sometimes these setups succeed; other times, they fail due to personality differences, conflicting practice philosophies, minor financial disputes, or even jealousy. However, one consistently successful strategy is sharing overhead costs. Reducing redundancies not only helps in swallowing some tough decisions (a lot of crow) but also maximizes financial efficiency and benefits the practice in numerous ways.

"Typical mergers occur when two competitors unite, thereby reducing overhead."
—Tony Fadell.

Increasing efficiency through strategies such as bulk purchasing, sharing staff like nurses and ancillary personnel, and utilizing common spaces for laboratories and equipment always yields better results. More participants generally mean enhanced benefits, following simple arithmetic.

2- Economy of Scale:

Consider electronic medical records systems, which are seldom inexpensive and typically run into six figures. Affording systems with comprehensive features not only enhances the work environment but also improves functionality, saving time and money and potentially correcting delays in accounts receivable. Thus, applying such economies of scale throughout the practice can significantly cut costs and boost financial returns.

"It's unwise to pay too much, but it's worse to pay too little. When you pay too much, you lose a little money—that's all. When you pay too little, you sometimes lose everything because the thing you bought was incapable of doing the thing it was bought to do."
—John Ruskin, from 19th Century's The Common Law of Business Balance

Implementing streamlined processes can be less costly in a larger practice compared to a smaller setting, allowing for the inclusion of advanced technology and equipment.

3- Bargaining Power:

"Negotiation requires the power to compel the other party."
—Saul D. Alinsky, American community activist and political theorist

A multispecialty practice serves as a convenient one-stop solution for patients, encompassing various specialists. This consolidation significantly strengthens bargaining power during contractual negotiations with insurance providers. The ability to influence these negotiations can prevent unfavorable outcomes that might occur in less comprehensive setups.

4- Geographical Considerations:

"Location, location, location."
—Harold Samuel.

The practice's location can significantly impact its accessibility and attractiveness. Situating the practice strategically can alleviate common logistical barriers for patients, such as traffic or distance, making the practice a preferable choice.

5- Diverse Services Offered:

The comprehensive nature of a multispecialty group means a wide range of healthcare services under one roof, leading to higher patient intake, shared costs, minimized liabilities, and increased geographic prominence. Multispecialty groups typically feature a larger team of physicians compared to their single-specialty counterparts, significantly enhancing service delivery and income.

6-Enhanced Healthcare Delivery:

Studies show that multispecialty groups provide better coordinated care, improved patient outcomes, and reduced healthcare costs. Patients have better access to a variety of specialists, ensuring continuous and comprehensive care, which translates to higher quality treatment across the board. This also benefits healthcare providers during contract renewals with payers due to improved service efficiency and patient satisfaction.

7- Quality of Life for Providers:

"The significant achievements of the world are accomplished by ordinary individuals who manage to work in an extraordinary manner."
—Gordon B. Hinckley

Multispecialty groups distribute workloads more evenly among providers, reducing individual administrative burdens and allowing providers to focus more on patient care. This setup improves the work-life balance and overall job satisfaction.

8- Financial Success:

In financial terms, multispecialty groups typically achieve higher revenues and profitability than single-specialty

THE POWER TO DETECT THE HIDDEN THREAT OF PERIPHERAL ARTERIAL DISEASE (PAD)



"PAD IS ASYMPTOMATIC IN 75% OF ELDERLY PATIENTS." [1]

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1. Sillesen, H., & Falk, E. (2011). Peripheral artery disease (PAD) screening in the asymptomatic population: why, how, and who?. Current atherosclerosis reports, 13(5), 390–395. https://doi.org/10.1007/s11883-011-0196-x
2. Diehm, C., Allenberg, J. R., Pittrow, D., Mahn, M., Tepohl, G., Haberl, R. L., Darius, H., Burghaus, I., Trampisch, H. J., & German Epidemiological Trial on Ankle Brachial Index Study Group (2009). Mortality and vascular morbidity in older adults with asymptomatic versus symptomatic peripheral artery disease. Circulation, 120(21), 2053–2061. https://doi.org/10.1161/CIRCULATIONAHA.109.865600

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groups. According to the MGMA, the median revenue for multispecialty groups in 2021 was significantly higher than that of their single-specialty counterparts. While outcomes can vary by region and competition, the trend towards forming larger multispecialty groups or health systems is becoming increasingly prevalent, driven by the complex dynamics of the healthcare industry.

9- Know the Beast You're Riding:
The foremost requirement in managing your multispecialty medical group is a thorough knowledge of the healthcare sector. This sector is continuously evolving—financially, legislatively, and technologically—driven by new technologies, regulations, and bureaucracy, leading to regularly updated reimbursement policies.

Medical knowledge is now doubling every few months, courtesy of collaborative research facilitated by the internet. This acceleration introduces new protocols, inventions, and clinical practices. Your familiarity with, and comprehension of, the latest technologies and procedures across various specialties must be up-to-date. Moreover, you should be aware of efficient inventory management practices.

Bureaucracy has evolved too, with physicians assuming significant roles within hospitals, such as serving on executive committees, overseeing disciplinary protocols, quality assurance, utilization review, and even human resources. Building and maintaining positive relationships with nursing, clerical, administrative, and other ancillary groups has become crucial. Keep your hat size handy, as you will be wearing many.

You must stay informed about all these diverse personnel, places, and processes. Ensuring that your medical group provides the best possible care hinges on your ability to adapt to this ever-evolving world. Staying current also includes complying with laws and regulations concerning patient information management and understanding the reimbursement policies and payment systems of insurance companies and government programs like Medicare and Medicaid.

10- Control the Beast You're Riding:
Ethical standards, rigorously enforced by the SEC, necessitate vigilant oversight to avoid inadvertent legal missteps in financial dealings. This underscores a well-known truth: being a doctor is difficult—mentally, physically, and emotionally. Yet, atop these challenges, you must also ensure that your multispecialty practice remains financially sound.

11- The Financials:
Managing the financial health of a multispecialty medical group is crucial. This management involves budgeting, accounting, and strategic financial planning. Understanding the costs associated with operating a medical group and the potential revenue streams is essential. The complexity of your organization requires attention to elements not typically dealt with at smaller scales, such as employee benefits including insurance, retirement funds, and possibly ownership shares, which are vital for maintaining employee satisfaction and loyalty.

Consider the tangible and intangible costs of losing seasoned employees—replacing them, training new hires, and earning their trust can be expensive. Generosity in employee compensation proves cost-effective in the long run, while frugality in this aspect may ultimately be more costly.

12- Human Resources:
Handling human resources is a critical aspect of managing a multispecialty medical group. This includes recruiting, hiring, managing, and training staff, as well as offering opportunities for employee development. A new sensitivity has emerged regarding respect for individuals concerning privacy, harassment, and the challenges that arise from interpersonal conflicts.

13- Marketing:
A robust marketing and advertising strategy is essential. You have constructed a substantial operation that competes with other large entities. Developing a strong brand identity for your medical group and crafting effective marketing materials and advertising campaigns are crucial for promoting your business and attracting new patients. Maintaining a commanding online presence through websites and social media is also key, requiring investment in professional expertise to manage these platforms effectively.

Forming a Multispecialty Group: Merging and Acquiring

"Strategic buyers, particularly health systems, are motivated to acquire practices to increase patient volumes and market share as well as to enhance negotiating power with payers."
—Stout Global Investment

Valuation:
The first step in building or buying a practice is the concept of valuation. Valuation is crucial in a merger or acquisition. It can be based on either fair market value or investment value, which considers possible economic benefits from expense reductions or revenue/profit adjustments. However, acquisition must be made via fair market value to comply with Stark laws and Anti-Kickback Statutes.

Valuation has three possible methods:

1. The income approach is either via a capitalized or discounted cash flow. While both determine value as equal to projected future free cash flow, the former is a single-period capitalization, and the latter is a multiperiod discounting.

2. The market approach is either via the Guideline Public Company (GPC) or the Merger and Acquisition (M&A) method. The former values the company by comparing

it with similar publicly traded companies, and the latter values the company compared to similar companies that have been in merger or acquisition "done deals."

3. The asset approach is based on appraisals of real and personal property appraisers when a practice's value falls below market value of the assets, i.e., when the practice is not expected to result in a positive cash flow.

There are also other facets to this jewel you're polishing, i.e., goodwill and brand worth; satellite ventures, such as buying into a laboratory for the practice; and shares that come with the purchase and their future dividends.

Physician mergers and acquisitions are predicted to be strong over the next several years, so there must be a good reason. It's the smart move today. However, hell is paved with the best intentions, so you must beware of "gotchas" like variable expenses, fixed expenses, and future staffing needs based on anticipated patient volume and growth.

Buying Into a Multispecialty Group

1- Medicare Multiple:
The above considerations will also figure into buying into a multispecialty group practice. You will want to look at what Medicare multiple is being used.

Wait… Whats a Medicare Multiple??

The term "Medicare multiple" isn't a standard term in financial or medical practice valuation contexts. It is an informal or non-standard metric used in specific discussions or scenarios, related to the valuation or financial assessment of healthcare practices where Medicare reimbursements play a significant role. This could involve calculating how many times over the Medicare reimbursement rates are factored into the overall valuation of the practice, reflecting its dependency on or the profitability of Medicare-related services. It might also refer to the practice's ability to optimize Medicare billing and maximize reimbursements, which could influence its financial attractiveness.

Example Scenario: Valuing a Medical Practice Based on Medicare Revenue:

Suppose there is a medical practice whose total annual revenue is $1,000,000. Of that revenue, $300,000, or 30%, comes directly from Medicare reimbursements. A potential buyer is evaluating how much to pay for the practice based primarily on its Medicare revenue, given its stability and predictability.

To determine the value, the buyer might consider using a "Medicare multiple" approach. This approach would involve setting a multiple to apply to the Medicare-specific portion of the revenue



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to reflect its importance, predictability, and potential for future growth or stability.

Calculating the Value:

- Medicare Revenue: $300,000
- Chosen Multiple: 3x (This multiple reflects the buyer's assessment of the risk and the expected return on investment. Higher multiples might be justified by a stable patient demographic, a critical location where Medicare patients are prevalent, or efficient management that maximizes Medicare billing.)

Calculation:
- $300,000 (Medicare Revenue) × 3 (Multiple) = $900,000

Total Valuation Approach: If the buyer evaluates the practice based not just on Medicare revenue but on a combination of factors, they might add a separate valuation for non-Medicare revenue. Suppose the rest of the revenue ($700,000) is valued at a 2x multiple due to its less predictable nature:

- $700,000 × 2 = $1,400,000
- Add the Medicare-based valuation: $1,400,000 + $900,000 = $2,300,000

2- Accounts Receivables:

Accounts receivable are self-explanatory. Certain businesses have protracted timelines for incoming accounts receivables. Obviously, they will want to incorporate that into your buy-in formula.

An uglier aspect of accounts receivables is outstanding bad debt. You're unlikely to get it after more than ninety days without payment. Once you go over one hundred and twenty days, you're not likely to see it…ever. (Alternatively, any debt owed that is less than ninety days is still considered current).

3- Hard Assets:

Hard assets are not factoring significantly at the current time. Physicians are in so much demand at this point that few dare risk losing a candidate by trying to fleece them of a few dollars for old computers and desks. Medical equipment and instruments may be more cost worthy. Buildings and real estate are the most important. I caution the readers to refrain from buying into real estate with a new job. Property investment is a commitment that's hard to undo, and should the partnership fall apart in the future, that will be hard to reverse.

4- Goodwill:

Goodwill is over. It is an anachronistic term that reminds older doctors like me of the days when we felt we had an edge over the candidate, when what we brought to the table was prizeworthy. Now, between groveling to the new doctor about how much we need them and bending over backward on vacation terms, goodwill is a term that cannot be brought up lest you upset your chances of a deal.

The Final Showdown

Once you have factored these points into your discussion, you come down to the brass tacks of buy-in. That's where the company's true value is formulated and presented to you by the actuaries and the accountants. Usually, and this applies to medical practice buy-ins and general business buy-ins, there are three formulas for evaluation of a business's strength and value:

1. **Earnings Before Interest, Taxes, Depreciation, and Amortization (EBITDA) Multiples:** This formula calculates the value of a business by multiplying its EBITDA by a certain multiple. The multiple used can vary depending on the industry, market conditions, and other factors. For example, if a business has an EBITDA of $500,000 and the multiple used is 5, its value would be $2.5 million.

2. **Discounted Cash Flow (DCF) Analysis:** This formula calculates the value of a business by approximating its future accruements and discounting them back to present value using a discount rate. The dis count rate represents the time value of money and the risk corresponding with the investment. This method requires forecasting future cash flows, which can be challenging but can also provide a more accurate valuation.

3. **Comparable Company Analysis (CCA):** This formula values a business by comparing it to similar companies recently sold or publicly traded. The key metrics used in this analysis are revenue, EBITDA, and net income. An estimated valuation range can be established by comparing the target business to similar businesses.

These are complex steps. Your accountants will guide you through these procedures. The outcome will be a prorated fee for your investment in the group, determined by your ownership stakes, your revenue-generating potential, and the demand for your specialty. This trifecta of business principles define your final buy-in amount. For example, a general medical doctor aiming to join a renowned Manhattan group might pay millions for this privilege, whereas a sought-after orthopedic surgeon in a small town could face no buy-in costs and might even receive a six-figure bonus to join. Ultimately, our circumstances determine our worth in both life and business. And in relationships, but that's a separate topic.

Overall, running, buying into, merging with, or acquiring a multispecialty medical group requires a combination of business acumen, industry knowledge, and a commitment

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to providing high-quality care to patients. High-quality care is the most essential ingredient. If you can't do well providing high-quality care, then you must be doing it wrong and are doomed. Yet, done right, it's a win-win for you and your patients.

By grasping the intricacies of the healthcare industry and its regulations, effectively managing the financial and human resource aspects of the business, and implementing a robust marketing and advertising strategy, you can establish or contribute to a thriving and enduring multispecialty medical group. Operating such a group is a demanding and intricate task that necessitates a deep understanding of the healthcare sector, a dedication to providing high-quality patient care, and a readiness to adapt to rapidly changing healthcare environments—similar to the swift color changes of a cuttlefish. Success and sustainability in a multispecialty medical group can be achieved by concentrating on the financial, operational, and marketing dimensions of the business and by cultivating a team of committed and proficient healthcare professionals.

Building a successful medical practice is fraught with challenges. In the words of Nelson Mandela, "Do not judge me by my successes, judge me by how many times I fell down and got back up again." But the end result, in the form of a successful venture, will be well worth the injuries.

ABOUT THE AUTHOR:

Dr. Shakeel Ahmed

Spanning two decades, Dr. Shakeel Ahmed, a gastroenterologist turned healthcare mogul, has transformed his vision into the Midwest's leading Ambulatory Surgery Centers network. His dual expertise in medical administration and surgical execution-gained from years of frontline experience-has been pivotal in mastering the complexities of the healthcare sector. Dr. Ahmed's notable contributions extend beyond the ASC sphere; he has played a key role in developing a comprehensive healthcare network, including a range of medical facilities, diagnostic centers, and surgical establishments across several states. His literary contributions includes 6 published books alongside hundreds of articles in prestigious national and international journals. He is a consultant for multiple governments on healthcare development and works as an advisor to various governments across four continents in the establishment of outpatient surgery centers.



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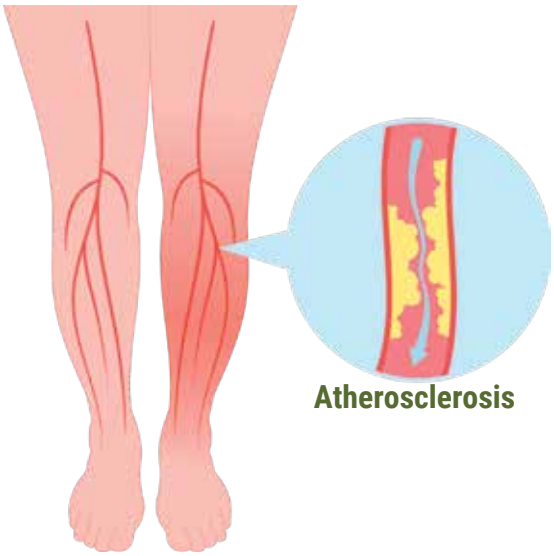
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Select Safety Information: Boxed WARNING

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES (ARIA)

- **Monoclonal antibodies directed against aggregated forms of amyloid beta, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications.**
  - **Apolipoprotein E ε4 (ApoE ε4) Homozygotes: Patients who are ApoE ε4 homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including LEQEMBI, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.**
- **Consider the benefit of LEQEMBI for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI.**

CONTRAINDICATION

LEQEMBI is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI. Reactions have included angioedema and anaphylaxis.

WARNINGS AND PRECAUTIONS

AMYLOID RELATED IMAGING ABNORMALITIES

- LEQEMBI can cause ARIA-E and ARIA-H. ARIA-E can be observed on MRI as brain edema or sulcal effusions, and ARIA-H as microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H and ARIA-E can occur together.
- ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. Reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

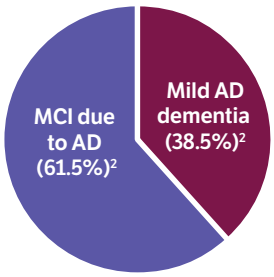
Please see additional Select Safety Information throughout and Brief Summary of Prescribing Information for LEQEMBI on the following pages, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb) 100 mg/mL
INJECTION FOR INTRAVENOUS USE

LEQEMBI® is proven to slow progression across the stages of Alzheimer's disease[1,2,4,5]

In Clarity AD (Study 2)

The majority of patients were in the earliest symptomatic stage, MCI due to AD[4,5]

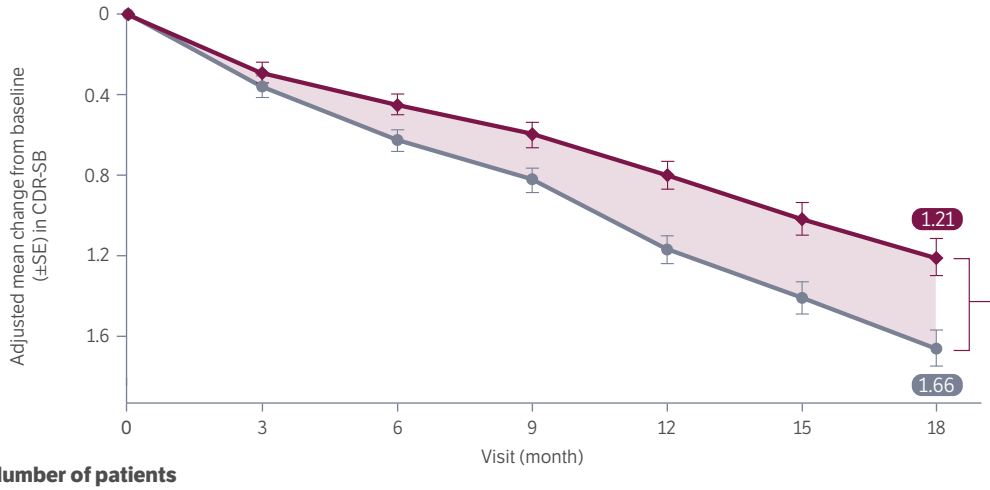


- **Study 2** Clarity AD was an 18-month, global, placebo-controlled, double-blind, parallel-group, randomized clinical trial of 1795 patients with MCI due to AD (n=528/859) or mild AD dementia (n=331/859) with confirmed Aβ pathology. Patients were randomized 1:1 to receive LEQEMBI 10 mg/kg (IV infusion) or placebo (IV infusion) once every 2 weeks[1,2]
- The **primary endpoint** was change from baseline at 18 months on the cognitive and functional CDR-SB scale[1]
- Key **secondary endpoints** included change from baseline at 18 months for the following measures: ADCS MCI-ADL (function), ADAS-Cog14 (cognition), and amyloid PET[1]

In Study 2

LEQEMBI met the primary endpoint at 18 months, demonstrating statistically significant efficacy[1]

CDR-SB: Change from baseline in cognition and function at 18 months



27% slowing of progression vs placebo; with increasing separation over time

P<0.0001

Number of patients							
LEQEMBI	859	824	798	779	765	738	714
Placebo	875	849	828	813	779	767	757

- LEQEMBI showed statistical significance at all time points beginning at 6 months
- Continued treatment with LEQEMBI demonstrated clinically meaningful slowing of cognitive and functional decline with increasing separation vs placebo through 18 months

MCI=mild cognitive impairment.

Select Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID RELATED IMAGING ABNORMALITIES (cont'd)

ARIA Monitoring and Dose Management Guidelines

- Obtain recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with LEQEMBI. Obtain an MRI prior to the 5th, 7th and 14th infusions.
- Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, temporarily discontinue treatment, or permanently discontinue LEQEMBI.
- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.
- There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic, but radiographically severe, ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E.

Please see additional Select Safety Information throughout and Brief Summary of Prescribing Information for LEQEMBI on the following pages, including Boxed WARNING.

LEQEMBI: Consistent results across all key secondary endpoints[1]

Key secondary endpoints (change from baseline at 18 months)[1-3,6]

37%	**26**%	~**56** CL
slowing of functional decline (2.0) compared with placebo *P*<0.0001	slowing of cognitive decline (-1.442) compared with placebo *P*<0.001	reduction compared to placebo, (LEQEMBI=22.4 CL, Placebo=78.6 CL) achieving plaque clearance* *P*<0.0001
LEQEMBI (N)= 783 **Placebo** (N)= 796	**LEQEMBI** (N)= 854 **Placebo** (N)= 872	**LEQEMBI** (N)= 354† **Placebo** (N)= 344†
Function ADCS MCI-ADL	**Cognition** ADAS-Cog14	**Amyloid beta** Brain amyloid PET

*Aβ plaque clearance (defined as <30 CL) achieved at the population level (mean) at 12 months for patients treated with LEQEMBI.[3]
†73 subjects were not included at 18 months (per statistical analysis plan) since their PET assessments were performed after receiving LEQEMBI in the Extension phase.[3]
Note: Based on pharmacodynamic analysis population (PET substudy population). Adjusted mean change from baseline, SE, and *P*-value are derived using MMRM with treatment group, visit, treatment group-by-visit interaction, clinical subgroup, use of AD symptomatic medication at baseline, ApoE ε4 carrier status, region, baseline value-by-visit interaction as fixed effects, and baseline value as covariate.[3]

CDR-SB is a validated outcome measure that consists of the following domains[2,7]:

Cognition



- Memory (eg, recalling recent/distant events)
- Orientation (eg, time, relationships, navigating familiar territory)
- Judgment/problem solving

Function



- Community affairs (eg, ability to work, socialize, and/or shop)
- Home and hobbies (eg, household tasks and activities)
- Personal care (eg, dressing, washing, using bathroom)

Scoring:

- Each domain can be scored as 0, 0.5, 1, 2, or 3, for a total scale range from 0-18[2,3]
- Higher scores indicate more advanced AD[2,3]
- MCI and mild AD dementia tend to score 0.5 or 1 in each domain[3]

EXPLORE the latest data at **LEQEMBIHCP.com**

Select Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID RELATED IMAGING ABNORMALITIES (cont'd)

Incidence of ARIA

- In Study 2, symptomatic ARIA occurred in 3% (29/898) of LEQEMBI-treated patients. Serious symptoms associated with ARIA were reported in 0.7% (6/898) of patients treated with LEQEMBI. Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation.
- Including asymptomatic radiographic events, ARIA was observed in LEQEMBI: 21% (191/898); placebo: 9% (84/897). ARIA-E was observed in LEQEMBI: 13% (113/898); placebo: 2% (15/897). ARIA-H was observed in LEQEMBI: 17% (152/898); placebo: 9% (80/897). There was no increase in isolated ARIA-H for LEQEMBI vs placebo.

ApoE ε4 Carrier Status and Risk of ARIA

- In Study 2, 16% (141/898) of patients in the LEQEMBI arm were ApoE ε4 homozygotes, 53% (479/898) were heterozygotes, and 31% (278/898) were noncarriers.
- The incidence of ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Among patients treated with LEQEMBI, symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes compared with 2% of heterozygotes and 1% of noncarriers. Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes, and approximately 1% of heterozygotes and noncarriers.
- The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

Radiographic Findings

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

LEQEMBI® (lecanemab-irmb) 100 mg/mL
INJECTION FOR INTRAVENOUS USE

Select Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID RELATED IMAGING ABNORMALITIES (cont'd)

Intracerebral Hemorrhage

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

Concomitant Antithrombotic Medication:

- In Study 2, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. The majority of exposures to antithrombotic medications were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of intracerebral hemorrhage was 0.9% (3/328 patients) in patients taking LEQEMBI with a concomitant antithrombotic medication at the time of the event compared to 0.6% (3/545 patients) in those who did not receive an antithrombotic. Patients taking LEQEMBI with an anticoagulant alone or combined with an antiplatelet medication or aspirin had an incidence of intracerebral hemorrhage of 2.5% (2/79 patients) compared to none in patients who received placebo.
- Because intracerebral hemorrhages >1 cm in diameter have been observed in patients taking LEQEMBI, additional caution should be exercised when considering the administration of anticoagulants or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI.

Other Risk Factors for Intracerebral Hemorrhage:

- Patients were excluded from enrollment in Study 2 for findings on neuroimaging that indicated an increased risk for intracerebral hemorrhage. These included findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage >1 cm in greatest diameter, >4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage. The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy, which has an increased risk for intracerebral hemorrhage. Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for intracerebral hemorrhage and in particular for patients who need to be on anticoagulant therapy.

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred in LEQEMBI-treated patients. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy.

INFUSION-RELATED REACTIONS

- In Study 2, infusion-related reactions were observed in LEQEMBI: 26% (237/898); placebo: 7% (66/897), and the majority of cases in LEQEMBI-treated patients (75%, 178/237) occurred with the first infusion. Infusion-related reactions were mostly mild (69%) or moderate (28%) in severity. Infusion-related reactions resulted in discontinuations in 1% (12/898) of LEQEMBI-treated patients. Symptoms of infusion-related reactions included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.
- In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Prophylactic treatment with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids prior to future infusions may be considered.

ADVERSE REACTIONS

- In Study 2, the most common adverse reaction leading to discontinuation of LEQEMBI was ARIA-H microhemorrhages that led to discontinuation in 2% (15/898) of patients treated with LEQEMBI compared to <1% (1/897) of patients on placebo.
- In Study 2, the most common adverse reactions reported in ≥5% of patients treated with LEQEMBI (N=898) and ≥2% higher than placebo (N=897) were infusion-related reactions (LEQEMBI: 26%; placebo: 7%), ARIA-H (LEQEMBI: 14%; placebo: 8%), ARIA-E (LEQEMBI: 13%; placebo: 2%), headache (LEQEMBI: 11%; placebo: 8%), superficial siderosis of central nervous system (LEQEMBI: 6%; placebo: 3%), rash (LEQEMBI: 6%; placebo: 4%), and nausea/vomiting (LEQEMBI: 6%; placebo: 4%).

Please see additional Select Safety Information throughout and Brief Summary of Prescribing Information for LEQEMBI on the following pages, including Boxed WARNING.

Aß=amyloid beta; ADAS-Cog14=Alzheimer's Disease Assessment Scale-Cognitive Subscale 14-item version; ADCS MCI-ADL=Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment; ApoE ε4=apolipoprotein E ε4; ARIA-E=amyloid-related imaging abnormality-edema; ARIA-H=amyloid-related imaging abnormality-hemosiderin deposition; CDR-SB=Clinical Dementia Rating-Sum of Boxes; CL=Centiloids; IV=intravenous; MMRM=Mixed Models for Repeated Measures; PET=positron emission tomography; SE=standard error.

References: 1. LEQEMBI (lecanemab-irmb) injection, for intravenous use [package insert]. Nutley, NJ: Eisai Inc. **2.** van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21. **3.** Iwatsubo T, Irizarry M, van Dyck C, Sabbagh M, Bateman RJ, Cohen S. Clarity AD: a phase 3 placebo-controlled, double-blind, parallel-group, 18-month study evaluating lecanemab in early Alzheimer's disease. Presented at: CTAD Conference; November 29-December 2, 2022; San Francisco, CA. **4.** Alzheimer's Association. 2023 Alzheimer's disease facts and figures. *Alzheimer's Dement*. 2023;18:1-122. **5.** Data on file. Clarity CSR. BAN2401-G000-301. Eisai Inc., Nutley, NJ. **6.** Data on file. QOL Clarity AD. BAN2401-G000-301. Eisai Inc., Nutley, NJ. **7.** Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. *Neurology*. 1993;43:2412-2414.

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LEQE-US2960 11/2023

LEQEMBI® (lecanemab-irmb) 100 mg/mL
INJECTION FOR INTRAVENOUS USE

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

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

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

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

ApoE ε4 Homozygotes

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

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

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Confirm the presence of amyloid beta pathology prior to initiating treatment

2.2 Dosing Instructions

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

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

2.3 Monitoring and Dosing Interruption for Amyloid Related Imaging Abnormalities

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

Monitoring for ARIA

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

Recommendations for Dosing Interruptions in Patients with ARIA

ARIA-E

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

Table 1: Dosing Recommendations for Patients with ARIA-E

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

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

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

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

ARIA-H

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

Table 2: Dosing Recommendations for Patients with ARIA-H

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

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

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

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

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

3 DOSAGE FORMS AND STRENGTHS

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

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Amyloid Related Imaging Abnormalities

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

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

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

Incidence of ARIA

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

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

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

ApoE ε4 Carrier Status and Risk of ARIA

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

Radiographic Findings

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

Table 3: ARIA MRI Classification Criteria

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

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

Intracerebral Hemorrhage

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

Concomitant Antithrombotic Medication

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

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

Other Risk Factors for Intracerebral Hemorrhage

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

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

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

Monitoring and Dose Management Guidelines

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

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

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

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

5.2 Hypersensitivity Reactions

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

5.3 Infusion-Related Reactions

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

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

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

6 ADVERSE REACTIONS

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

- Amyloid Related Imaging Abnormalities *[see Warnings and Precautions (5.1)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

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

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

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

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

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

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

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

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

Less Common Adverse Reactions

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

8.2 Lactation

Risk Summary

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

17 PATIENT COUNSELING INFORMATION

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

Amyloid Related Imaging Abnormalities

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

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

Patient Registry

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

Hypersensitivity Reactions

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

Infusion-Related Reactions

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

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Printed in USA/August 2023 LEQE-US2713 08/2023



METRIX® COVID-19 TEST – A MOLECULAR LAB ANYWHERE AND EVERYWHERE

From Sekisui

The Metrix® COVID-19 is a novel technology includes clinical claims for symptomatic and asymptomatic individuals, along with dual-sample types for nasal or saliva, allowing for an enhanced point-of-care testing experience. The reader is compact and robust, it's ideal for professional use in diverse locations, including clinics and mobile health units. It's a maintenance free device with no calibration step required.

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BE PREPARED FOR RESPIRATORY SEASONS WITH THE OSOM® COVID-19 ANTIGEN RAPID TEST

From Sekisui

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow immunoassay that detects the SARS-CoV-2 nucleocapsid protein with a nasal swab in only 15 minutes at the point-of-care. The test is intended to be used by healthcare professionals or operators on patients suspected of COVID-19 within the first 7 days of symptom onset. The clinical performance compares favorably against polymerase chain reaction methodology, with a positive percent agreement of 95.1% and a negative percent agreement of 97%.

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



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Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide Hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Monitor glycemic control in patients with diabetes and screening for kidney disease in patients at-risk, in-office. Enable real-time consultation, eliminating loss to follow-up. Improve the patient experience and overall outcome by providing actionable results in minutes.

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QUANTAFLO® PAD

From Semler Scientific

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

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

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NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

From Nova Biomedical

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

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The LumiraDx SARS-CoV-2 Ag test utilizes next-generation microfluidic technology, bringing lab-comparable performance to the point of care.

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*The LumiraDx SARS-CoV-2 Ag test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated, or authorization is revoked sooner. S-COM-ART-02381 R3 2022/11

PERIPHERAL ARTERIAL DISEASE



4117

QUANTAFLO® PAD

From Semler Scientific

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

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

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Your Patients Trust YOU To Find Their Peripheral Artery Disease
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The simpleABI Cuff-Link System is Easy to Learn and Use.
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- Medicare reimbursements vary by exam and location, averaging from $91 to $174.

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SYNDROMIC TESTING



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

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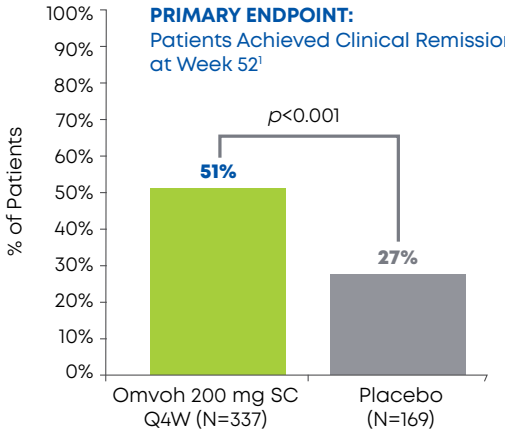
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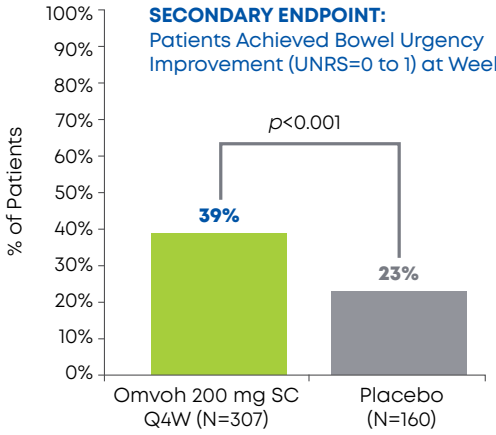
For your adult patients with moderately to severely active ulcerative colitis (UC) who had inadequate response to their current treatment[1]

MAKE THE URGENT CHANGE WITH OMVOH

AMONG PATIENTS WHO ACHIEVED CLINICAL RESPONSE WITH OMVOH AT WEEK 12[1]

Omvoh demonstrated sustained clinical remission and reduced bowel urgency at Week 52[1]





Nearly 2 in 3 patients taking Omvoh achieved clinical response at Week 12[1]

65% of patients (n=517/795) taking Omvoh achieved clinical response* after 12 weeks of induction dosing vs 43% (n=115/267) with placebo (secondary endpoint), and nearly 1 in 4 (24%, n=191/795) achieved clinical remission[a] vs 15% (n=40/267) with placebo (primary endpoint).[1]

[a]Clinical remission based on mMS is defined as: SF=0 or 1, RB=0, and centrally read ES=0 or 1 (excluding friability).[1]
*Clinical response is defined as a decrease in the mMS of ≥2 points with ≥30% decrease from baseline, and either a decrease of ≥1 point in RB from baseline or RB=0 or 1.[1]

INDICATION

Omvoh™ is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.[1]

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

Please see Important Safety Information below.

UC-1 AND UC-2 TRIAL DESIGN

Omvoh was studied in two Phase 3, randomized, double-blind, placebo-controlled clinical trials of adult patients with moderately to severely active UC. Patients (N=1279) were randomized 3:1 to receive Omvoh 300 mg IV infusion or placebo every 4 weeks (Q4W) for 12 weeks (Week 0, 4, and 8) in the induction study (UC-1). Patients who achieved clinical response with Omvoh at Week 12 in UC-1 (N=581) were re-randomized 2:1 to receive Omvoh 200 mg SC injection or placebo Q4W for 40 weeks in the maintenance study (UC-2) (52 weeks of continuous therapy). The primary endpoint was the proportion of patients in clinical remission at Week 12 in UC-1 and Week 40 in UC-2.[1]

At baseline of UC-1, all patients had inadequate response, loss of response, or intolerance to at least one corticosteroid, immunomodulator, biologic treatment (TNF blocker, vedolizumab), or tofacitinib. In UC-2, patients who were on concomitant UC therapies during UC-1 were required to continue on stable doses of oral aminosalicylates and immunomodulator agents. Corticosteroid tapering was required for patients who were receiving oral corticosteroids at baseline and achieved clinical response in UC-1.[1]

Patients with an mMS of 5 to 9 at baseline of UC-1 were included for efficacy analyses. Patients had a median mMS of 7, and 58% had severely active disease (mMS 7 to 9). Patients' baseline therapies included 41% of patients receiving oral corticosteroids, 24% receiving immunomodulators, and 75% receiving aminosalicylates. Patients' prior treatment experiences include: 57% were biologic- and JAKi-naive, 41% had failed at least one biologic, 3% had failed a JAKi, and 2% had previously received but had not failed a biologic or JAKi.[1]

Bowel urgency was assessed using an Urgency Numeric Rating Scale (UNRS) ranging from 0 (no urgency) to 10 (worst possible urgency) during UC-1 and as a secondary endpoint in UC-2. Bowel urgency improvement was evaluated as the proportion of patients with a baseline UNRS weekly average score of ≥3 achieving a weekly average score of 0 to 1 at Week 12 in UC-1 and Week 40 in UC-2.[1,2,4]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections

Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.



Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity
Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial patient following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations
Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS
Most common adverse reactions (≥2%) associated with Omvoh treatment are upper respiratory tract infections and arthralgia during induction, and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance.

MR HCP ISI UC APP

See Brief Summary of Prescribing Information on subsequent pages. See Instructions for Use included with the device.

ES=endoscopic subscore; IV=intravenous; mMS=modified Mayo score; Q4W=every 4 weeks; RB=rectal bleeding subscore; SC=subcutaneous; SF=stool frequency subscore; TNF=tumor necrosis factor; UC=ulcerative colitis; UNRS=Urgency Numeric Rating Scale.

References: 1. Omvoh (mirikizumab-mrkz). Prescribing Information. Lilly USA, LLC. **2.** D'Haens G, Dubinsky M, Kobayashi T, et al. Mirikizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2023;388(26):2444-2455. doi:10.1056/NEJMoa2207940 **3.** Data on File. DOF-MR-US-0018. Lilly USA, LLC. **4.** Dubinsky MC, Irving PM, Panaccione R, et al. Incorporating patient experience into drug development for ulcerative colitis: development of the Urgency Numeric Rating Scale, a patient-reported outcome measure to assess bowel urgency in adults. *J Patient Rep Outcomes*. 2022;6(1):31. doi:10.1186/s41687-022-00439-w.

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Omvoh™ (mirikizumab-mrkz) injection, for intravenous or subcutaneous use

Brief Summary: Consult the package insert for complete prescribing information.

INDICATIONS AND USAGE
Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

CONTRAINDICATIONS
Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritis, were reported during induction [see *Adverse Reactions*]. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections
Omvoh may increase the risk of infection *[see Adverse Reactions]*.

Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh.

Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment.

In clinical trials, subjects were excluded if they had evidence of active TB, a past history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity
A case of drug-induced liver injury (alanine aminotransferase [ALT] 18x the upper limit of normal (ULN), aspartate aminotransferase [AST] 10x ULN, and total bilirubin 2.4x ULN) in conjunction with pruritus was reported in a clinical trial subject following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline.

Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management.

Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations
Avoid use of live vaccines in patients treated with Omvoh. Prior to initiating therapy with Omvoh, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS
The following topics are also discussed in detail in the Warnings and Precautions section:
Hypersensitivity Reactions
Infections
Tuberculosis
Hepatotoxicity

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

Omvoh was studied up to 12 weeks in subjects with moderately to severely active ulcerative colitis in a randomized, double-blind, placebo-controlled induction study (UC-1). In subjects who responded to induction therapy in UC-1, long-term safety up to 52 weeks was evaluated in a randomized, double-blind, placebo-controlled maintenance study (UC-2) and a long-term extension study *[see Clinical Studies]*.

In the induction study (UC-1), 1279 subjects were enrolled of whom 958 received Omvoh 300 mg administered as an intravenous infusion at Weeks 0, 4, and 8. In the maintenance study (UC-2), 581 subjects were enrolled of whom 389 received Omvoh 200 mg administered as a subcutaneous injection every 4 weeks.

Table 1 summarizes the adverse reactions reported in at least 2% of subjects and at a higher frequency than placebo during UC-1.

Table 1: Adverse Reactions[a] in Subjects with Ulcerative Colitis through Week 12 in a Placebo-Controlled Induction Study (UC-1)

Adverse Reactions	OMVOH 300-mg Intravenous Infusion[b] N=958 n (%)	Placebo N=321 n (%)
Upper respiratory tract infections[c]	72 (8%)	20 (6%)
Arthralgia	20 (2%)	4 (1%)

[a] Reported in at least 2% of subjects and at a higher frequency than placebo.
[b] Omvoh 300 mg as an intravenous infusion at Weeks 0, 4, and 8.
[c] Upper respiratory tract infections includes related terms (e.g., COVID-19, nasopharyngitis, pharyngitis, rhinitis, sinusitis, and upper respiratory tract infection).

In the induction study (UC-1), infusion-related hypersensitivity reactions were reported by 4 (0.4%) subjects treated with Omvoh and 1 (0.3%) subject treated with placebo.

Table 2 summarizes the adverse reactions reported in at least 2% of subjects and at a higher frequency than placebo during the 40-week controlled period of UC-2.

Table 2: Adverse Reactions[a] in Subjects with Ulcerative Colitis through Week 40 In a Placebo-Controlled Maintenance Study (UC-2)

Adverse Reactions	OMVOH 200-mg Subcutaneous Injection[b] N=389 n (%)	Placebo N=192 n (%)
Upper respiratory tract infections[c]	53 (14%)	23 (12%)
Injection site reactions[d]	34 (9%)	8 (4%)
Arthralgia	26 (7%)	8 (4%)
Rash[e]	16 (4%)	2 (1%)
Headache	16 (4%)	2 (1%)
Herpes viral infection[f]	9 (2%)	1 (1%)

[a] Reported in at least 2% of subjects and at a higher frequency than placebo
[b] Omvoh 200 mg as a subcutaneous injection at Week 12 and every 4 weeks thereafter for up to an additional 40 weeks.
[c] Upper respiratory tract infections includes related terms (e.g., COVID-19, nasopharyngitis, pharyngitis, rhinitis, sinusitis, and upper respiratory tract infection).
[d] Injection site reactions includes related terms (e.g., erythema, hypersensitivity, pain, reaction, and urticaria at the injection site).
[e] Rash is composed of several similar terms.
[f] Herpes viral infection includes related terms (e.g., herpes zoster, herpes simplex, and oral herpes.)

Infections
In UC-1 through Week 12, infections were reported by 145 (15%) subjects treated with Omvoh 300 mg and 45 (14%) subjects treated with placebo. Serious infections were reported by less than 1% in both groups. Serious infections in the Omvoh group included intestinal sepsis, listeria sepsis, and pneumonia.

In the maintenance study (UC-2) through Week 40 (a total of 52 weeks of treatment), infections were reported by 93 (24%) subjects treated with Omvoh 200 mg and 44 (23%) subjects treated with placebo. A case of COVID-19 pneumonia was reported as a serious infection in the Omvoh group.

Hepatic Enzyme Elevations
In UC-1 through Week 12, alanine aminotransferase (ALT) ≥5X ULN was reported by 1 (0.1%) subject treated with Omvoh 300 mg and 1 (0.3%) subject treated with placebo. Aspartate aminotransferase (AST) ≥5X ULN was reported by 2 (0.2%) subjects treated with Omvoh 300 mg and no subject treated with placebo. These elevations have been noted with and without concomitant elevations in total bilirubin.

In the maintenance study (UC-2) through Week 40 (a total of 52 weeks of treatment), 3 (0.8%) subjects treated with Omvoh 200 mg reported ALT ≥5X ULN and 3 (0.8%) subjects reported AST ≥5X ULN; with or without concomitant elevations in total bilirubin. No subjects treated with placebo experienced similar elevations *[see Warnings and Precautions]*.

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for intravenous or subcutaneous use MR HCP BS UC APP

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Omvoh during pregnancy. Pregnant women exposed to Omvoh and healthcare providers are encouraged to call Eli Lilly and Company at 1-800-Lilly-Rx (1-800-545-5979).

Risk Summary

Available data from case reports of mirikizumab-mrkz use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Although there are no data on mirikizumab-mrkz, monoclonal antibodies can be actively transported across the placenta, and mirikizumab-mrkz may cause immunosuppression in the in utero-exposed infant. An enhanced pre- and post-natal development study conducted in pregnant monkeys at a dose 69 times the maximum recommended human dose (MRHD) revealed no adverse developmental effects to the developing fetus, or harm to infant monkeys from birth through 6 months of age. There are risks of adverse pregnancy outcomes associated with increased disease activity in women with inflammatory bowel disease *(see Clinical Considerations)*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and Embryo/Fetal Risk

Published data suggest that the risk of adverse pregnancy outcomes in women with inflammatory bowel disease (IBD) is associated with increased disease activity. Adverse pregnancy outcomes include preterm delivery (before 37 weeks gestation), low birth weight (less than 2500 g) infants, and small for gestational age at birth.

Fetal/Neonatal Adverse Reactions

Transport of endogenous IgG antibodies across the placenta increases as pregnancy progresses, and peaks during the third trimester. Because mirikizumab-mrkz may interfere with immune response to infections, risks and benefits should be considered prior to administering live vaccines to infants exposed to Omvoh in utero. There are no data regarding infant serum levels of mirikizumab-mrkz at birth and the duration of persistence of mirikizumab-mrkz in infant serum after birth. Although a specific timeframe to delay live virus immunizations in infants exposed in utero is unknown, a minimum of 2 months after birth should be considered because of the half-life of the product.

Data

Animal Data

An enhanced pre- and postnatal development study was conducted in cynomolgus monkeys administered mirikizumab-mrkz by intravenous injection during organogenesis to parturition at a dose of 300 mg/kg twice weekly (69 times the MRHD based on exposure comparisons). Mirikizumab-mrkz crossed the placenta in monkeys. No maternal toxicity was noted in this study. No mirikizumab-mrkz-related effects on morphological, functional, or immunological development were observed in infant monkeys from birth through 6 months of age. However, incidences of embryo/fetal loss were higher in the treated groups compared to control (6.7% [1 of 15] in controls vs 26.7% [4 of 15] at 300 mg/kg (69 times the MRHD, based on exposure comparisons) but were within the range of historical control data. Following delivery, most adult female cynomolgus monkeys and all infants from the mirikizumab-mrkz-treated group had measurable serum concentrations up to 28 days postpartum. In the infant monkeys, mean serum concentrations were approximately 4.8 times the respective mean maternal concentrations.

Lactation

Risk Summary

There are no data on the presence of mirikizumab-mrkz in human milk, the effects on the breastfed infant, or the effects on milk production. Endogenous maternal IgG and monoclonal antibodies are transferred in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to mirikizumab-mrkz are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omvoh and any potential adverse effects on the breastfed infant from Omvoh or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of Omvoh have not been established in pediatric patients.

Geriatric Use

Of the 795 Omvoh-treated subjects in the two clinical trials, 64 subjects (8%) were 65 years of age and older, while 10 subjects (1%) were 75 years of age and older. These clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger adult subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects. No clinically meaningful differences in the pharmacokinetics of mirikizumab-mrkz were observed in subjects 65 years of age and older compared to younger adult subjects *[see Clinical Pharmacology]*.

DOSING

Recommended Dosage

Induction Dosage

The recommended induction dosage of Omvoh is 300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8 *[see Dosage and Administration]*.

Maintenance Dosage

The recommended maintenance dosage of Omvoh is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter *[see Dosage and Administration]*.

PATIENT COUNSELING INFORMATION

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

Hypersensitivity Reactions

Advise patients to discontinue Omvoh and seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*.

Infections

Advise patients that Omvoh may lower the ability of their immune system to fight infections and to contact their healthcare provider immediately if they develop any symptoms of infection *[see Warnings and Precautions]*.

Tuberculosis

Advise patients to contact their healthcare provider if they experience symptoms suggestive of TB (e.g., unexplained fever, cough, or difficulty breathing) *[see Warnings and Precautions]*.

Hepatotoxicity

Inform patients that Omvoh may cause liver injury. Advise patients to seek immediate medical attention if they experience symptoms suggestive of liver dysfunction (e.g., unexplained rash, nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine) *[see Warnings and Precautions]*.

Immunizations

Advise patients that vaccination with live vaccines is not recommended during Omvoh treatment and immediately prior to or after Omvoh treatment. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Instruct patients to inform their healthcare provider that they are taking Omvoh prior to receiving a vaccination *[see Warnings and Precautions]*.

Pregnancy

Advise patients who are exposed to Omvoh during pregnancy to contact Eli Lilly and Company *[see Use in Specific Populations]*.

Administration

Instruct patients in preparation and administration of Omvoh, including choosing anatomical sites for subcutaneous administration, and proper subcutaneous injection technique. Instruct patients in the technique of pen disposal *[see Instructions for Use]*.

Instruct patients or caregivers to administer two 100-mg prefilled pens to achieve the full 200-mg dose of Omvoh.

Additional information can be found at www.Omvoh.com

See Instructions for Use accompanying the product device.

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THE HAMPTONS *of Hollywood*

BY BRANDI BROWER, TRAVEL EDITOR



You've heard of Charles Dickens's famed novel "A Tale of Two Cities." With a creative license, I'm writing "A Review of Two Regions," a two-part series comparing and contrasting the Southern and Northern areas of the Golden State—specifically, the sun-drenched sandy city and conservative enclave of California, Newport Beach, vs. the majestic mountain magic and serene scene of South Lake Tahoe. Both beautiful. Both are variants of vacation vibes. It is a tale of two distinctly different destinations in one state.

The first stop is Orange County. Newport Beach is 80 miles north of San Diego and 40 miles southeast of downtown Los Angeles. With its proximity to Hollywood, historically, the calm waters of Newport have been a protective harbor for movie stars who want an easy escape. Some stars from Hollywood's Golden Age made Newport Beach their home, nicknaming it "The Hamptons of Hollywood." Just off the Pacific Coast Highway, driving on the Mariner's Mile, passing multi-million dollar yachts on my right and multi-million dollar homes to my left, I pull into the Balboa Bay Resort, imagining the summers spent here by stars from a bygone era like Bogie and Bacall.

The Balboa Bay Resort, a luxurious haven, shares its grounds with the members-only Balboa Bay Club. This private club, once the exclusive hangout of Tinseltown's elite, including John Wayne, Greta Garbo, and Clark Gable, exudes an air of privilege and exclusivity, making you feel like a part of an elite circle. Nestled on 15 prime waterfront acres along the Bay, this coveted real estate perfectly captures the nautical Newport vibe, with mega-yachts moored side by side. The spirit of old Hollywood starlets and influential politicians fills the halls, gracing the walls with black-and-white photos of the rich, famous, and almost famous who frequented the hotspot. It's an experience that immerses you in the nostalgia of the mid-20th century, leaving you feeling like those were the good old days.

The resort offers 159 rooms, 10 of which are suites, and three room categories depend on location and view. All accommodations are spacious, providing ample room to relax and unwind, and boast private furnished balconies, flat-screen TVs with premium channels, white Frette linens on pillow-top mattresses, marble bathrooms with dual sinks and walk-in showers, and writing desks. I was grateful for my Bayview room, which was the perfect perch to watch the water action and entice exploration.

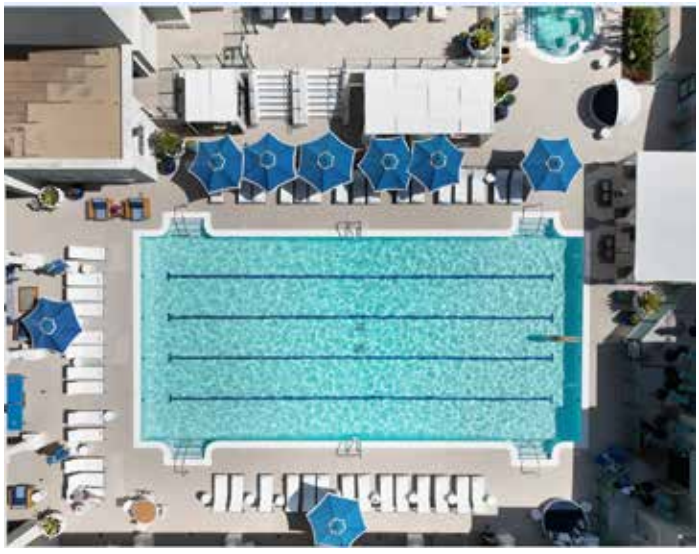
Newport Beach can claim to be the largest recreational harbor on the West Coast. Home to 9000 vessels of all shapes and sizes, from adorable Duffy boats to mega yachts, it's not just a harbor; it's an H20 playground, perfect for those seeking an active and fun-filled vacation. Top of my list for adventure was to captain one of the cute electric 12-passenger Duffy boats the resort rents. No boating license is required because it only goes 6 miles per hour, like driving a golf cart on water. With Bluetooth capabilities, you can select your playlist and troll around the harbor, looking at the backyards of the beautiful homes abutting the Bay or checking out the backsides of the boats and the creative names of the vessels: Ex Ta Sea, Why Knot, Dances with Waves are just a few of the punny monikers we found.

What better way to top off a sunset boat cruise than enjoying bayside bites under the bistro lights and al fresco dining at its finest with modern-design fire pits and comfy couches? The celebrated onsite signature A+O restaurant/bar, Anchors & Oceans, is the answer. As the sun dips down, the spirits ramp up with live music, creative craft cocktails, and themed menu offerings: Taco & Tequila Tuesdays, Western Wednesdays, and Sushi & Sake Saturdays are clever culinary offerings. The rap around decking gives optimal viewing for sun settings and boat watching; the blue and white color palette is accentuated with umbrellas in a bright yellow. If the weather dips down to the lower 60s (Newport Beach has an average year-round temperature between 65 and 75), the staff will turn on one of the several outdoor patio heaters. California casual in design and cuisine, headed by 17-year-veteran Executive Chef Prabeen Prathapan, the A+O is a favorite scene for locals and guests. Sundays are reserved for the best brunch in town, held weekly in the waterfront Lighthouse room for a succulent seafood spread, made-to-order omelet station, charcuterie, and patisserie galore.

It's said that it never rains in southern California; in my experience, that's a true statement. I wake to another beautiful sunny day, stop at the Blend Cafe, a grab-n-go eatery at the resort, and take my overnight oats and chai latte out to the pool. The year-round heated open-air Olympic-sized pool with hydro-spa, cozy lounge chairs, and private cabanas are inviting. But today, a beach cruiser bike ride is the quintessential SoCal experience that calls. The concierge desk sets me up for success with a map



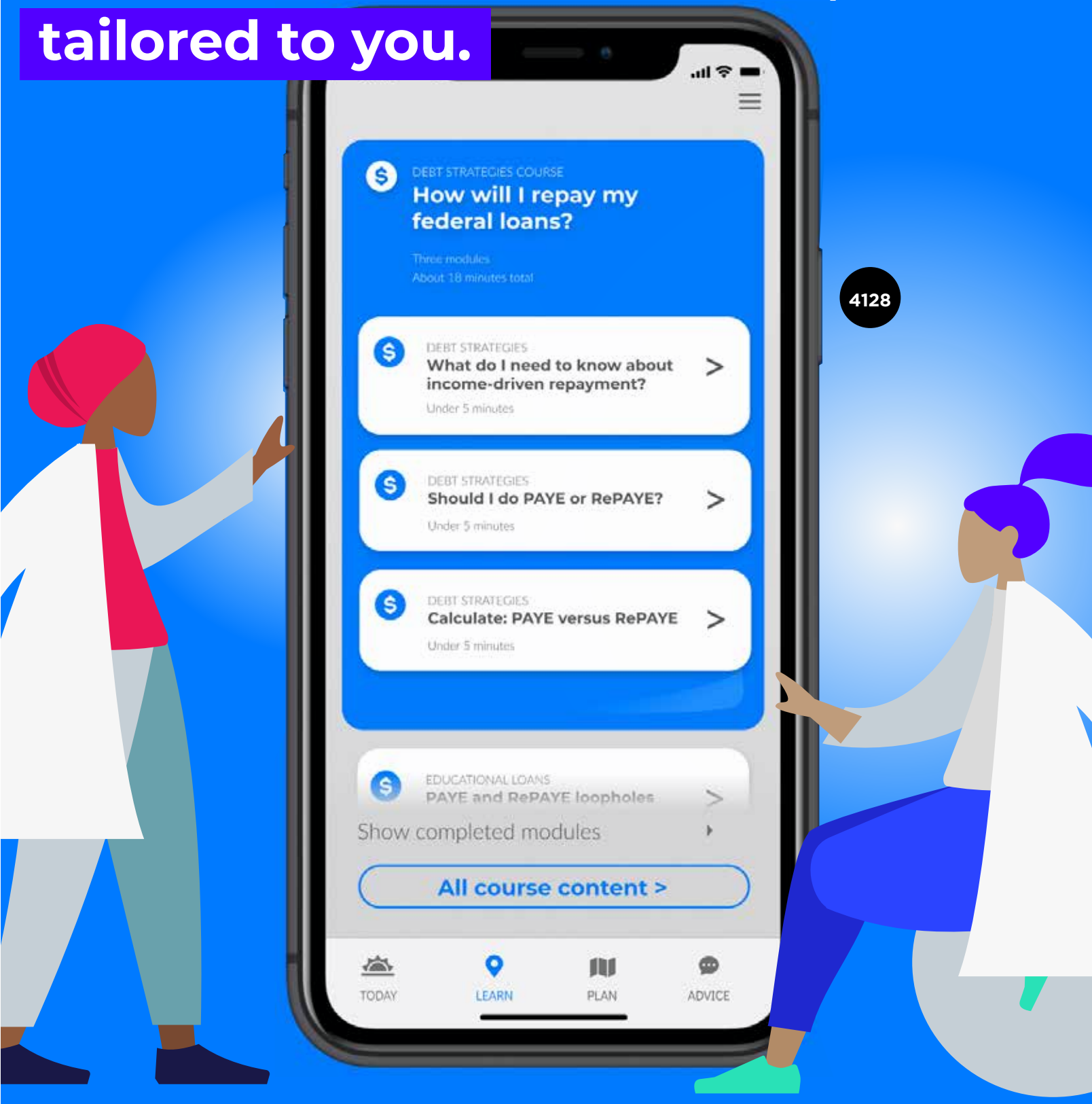




and suggestions for seeing the sites. One of Newport Beach's unique features is its eight islands in Newport Harbor. These islands, primarily residential with some commercial areas, add a distinct charm. Each island has its character and history, waiting to be explored by those who seek a deeper understanding of this beautiful destination.

I decided to make the loop around most of Newport Harbor. The excursion is relatively flat, which is great because even though electric bikes were available, I chose the classic ride instead. I cross the bridge to Little Balboa Island and stop to enjoy a frozen banana at the original stand since 1940, a nod to any Arrested Development fans reading this. There are cute shops and the Balboa Island Museum and Historical Society. Better still, the charming streets, rows, and rows of beautifully designed homes are enjoyable to browse. Next, the Ferry ride across the harbor over to the Fun Zone. This 80-year-old landmark has fun fair fare with burgers, ice cream, pizza stands, arcades, and a few rides, including a colorful Ferris wheel. I ride down to the extreme Southeast corner of Balboa Peninsula to The Wedge, an excellent spot for powerful surf with the potential for 30-foot waves; it's a fantastic place to watch and admire the talented surfers who dare to tackle the sweet swells. Back on the bike, I take the path stretching along the Peninsula, from the Balboa Pier to the Newport Pier, a beautiful opportunity to take in the incredible views of both sea and sand. I hit the Lido Marina Village to window shop in the chic stores and pass by the Nobu and Malibu Farm restaurants, which are tempting. I'm hungry, but I pedal onward. There's something special about this area: the idyllic weather, glittering water, and so many fun things to explore; the proximity to the Balboa Bay Resort is ideal, and it's no wonder its famous Balboa Bay Club is known as the "Host of the Coast." The charm and beauty of the area are a welcoming breath of fresh sea air.

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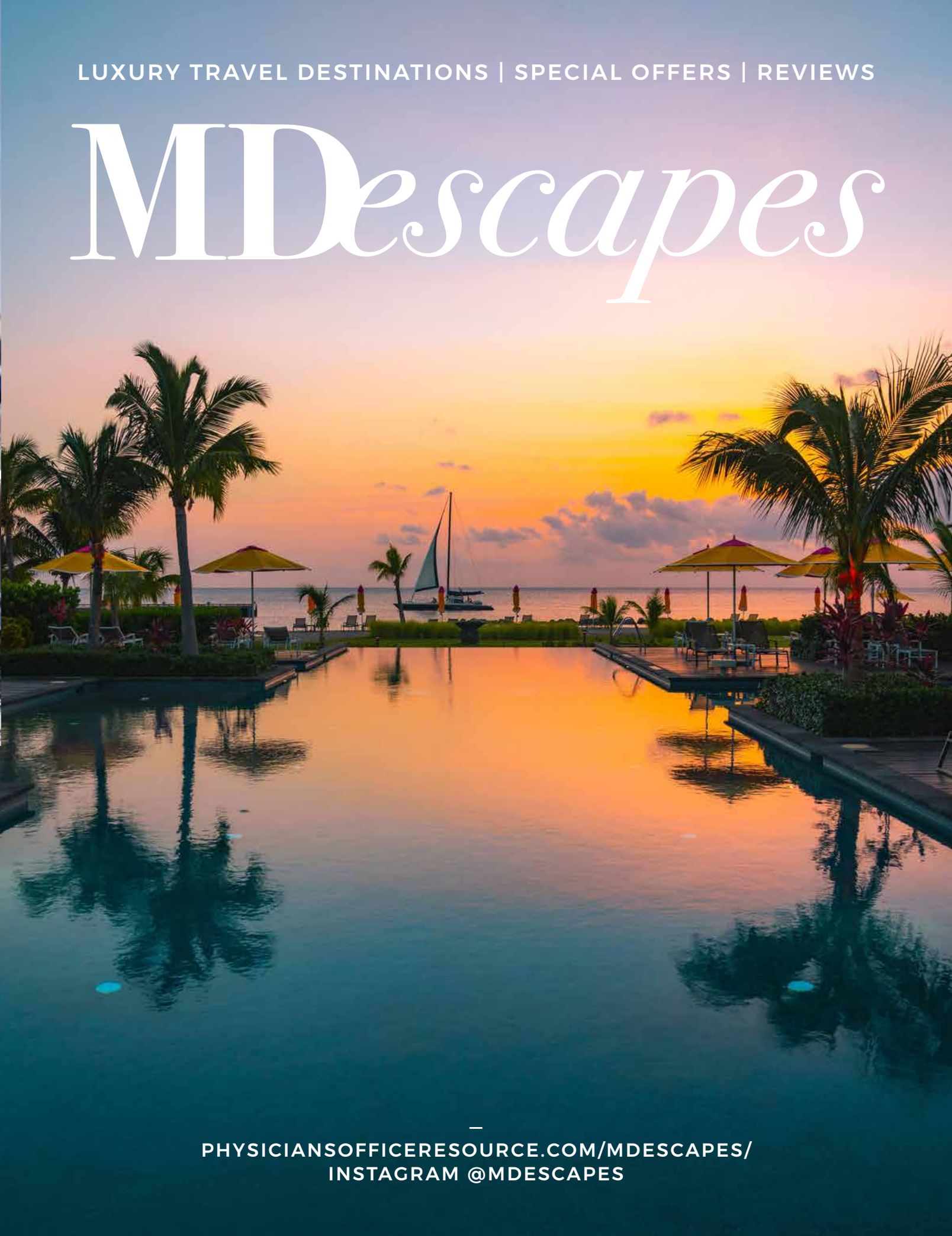
After a long but lovely peddle-pushing afternoon, some pampering may be on the agenda. Wellness is just a walk away in the Balboa Bay Club building, where skin care, massage, and body treatments are some of the spa services available. After enjoying the sauna, whirlpool, steam room, and relaxing lounge, spoil yourself just a little bit more with a perfect blowout at the Drybar, conveniently located on the premises. For those who don't need your hair done, spoil yourself with a libation at the Oasis Pool bar, offering zero-proof concoctions and clever cocktails with cute names.

When you wake up the next day, the weather will undoubtedly be perfect, the sun will be shining, and the tide will be high, another great start for more Southern California adventures. Balboa Bay Resort has the ideal location to travel in any direction and make memories. If the Fun Zone isn't your speed, nearby Disneyland, Universal Studios, Knotts Berry Farm, and Legoland are options. If you're a museum enthusiast, visit the Lyon Air Museum, Marconi Automotive Museum, and Orange Country Art Museum. A romantic at heart, take a boat cruise, hike down with a picnic lunch to Crystal Cove, or if the kids are in tow, the resort will plan a family beach day for you with all the necessities. If you like golfing, there are several golf courses to choose from. If you enjoy shopping, Fashion Island is a famous shopping stop. If you decide not to leave the comfort of your bayside retreat, you still have options. Kayaking, paddleboarding, fitness equipment, and classes are available, and you can pick up a little something for yourself at the Bayside Boutique or Spa Boutique onsite.

Balboa Bay Resort is ranked #1 for Newport Beach Resorts by the U.S. News and World Report, the only Forbes Four-Star, AAA Four-Diamond waterfront resort in Newport Beach. The iconic waterfront property has been here for over 75 years, a venerable sentinel overlooking the Bay for all the yachts that pass by, a revered respite for those that enter its gates. The laid-back luxury that is the Balboa Bay Resort has been open for just 20 years, yet it's an esteemed hotel that celebrates all that is coastal, Californian, and cool. Classic cool, like Bogie and Bacall.

LUXURY TRAVEL DESTINATIONS | SPECIAL OFFERS | REVIEWS

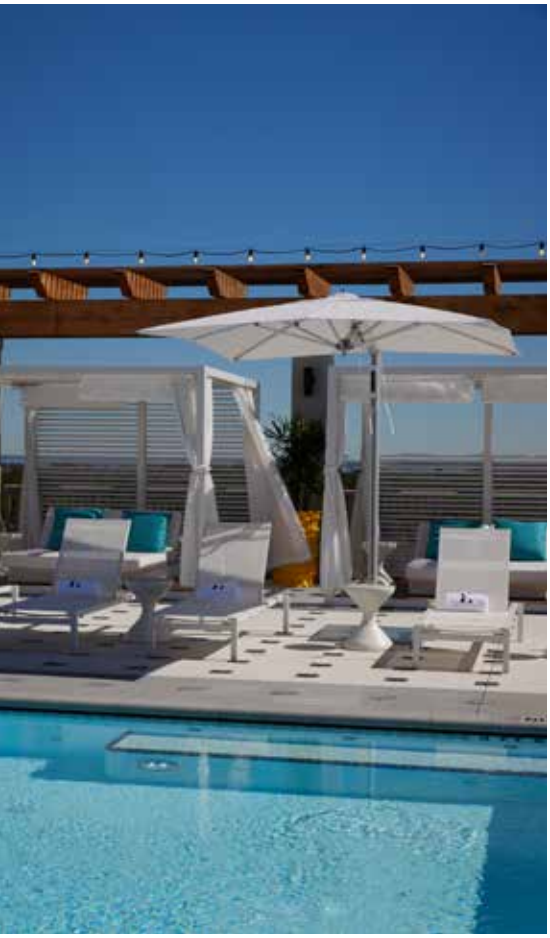
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