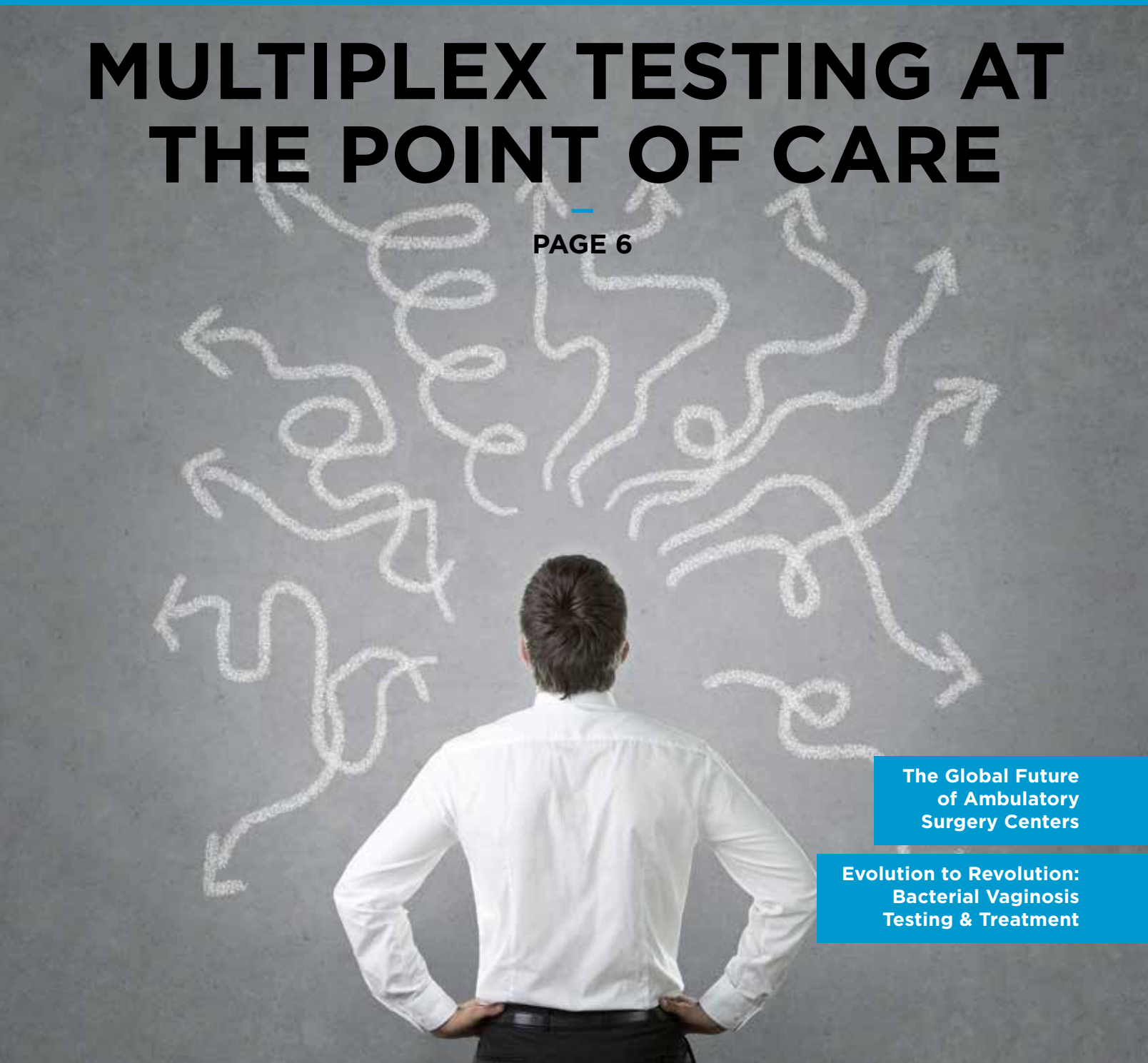
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MULTIPLEX TESTING AT THE POINT OF CARE

PAGE 6



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Evolution to Revolution: Bacterial Vaginosis Testing & Treatment

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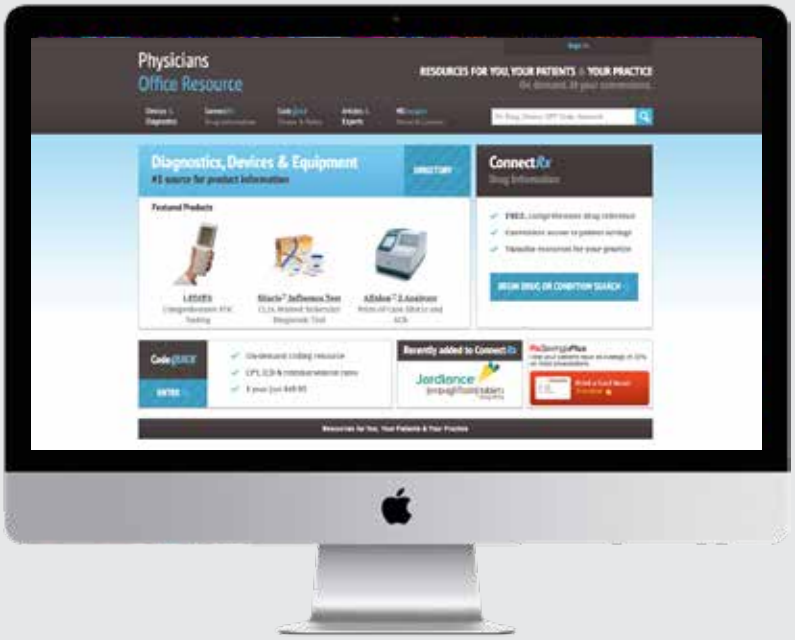
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6

Multiplex Testing at the Point of Care

Is it influenza, COVID, RSV, or some other respiratory infection? HCPs are faced with these questions every day as patients fill their exam rooms with coughs, fevers, and congestion.

14

The Global Future of Ambulatory Surgery Centers

Ambulatory Surgery Centers are no longer a peripheral innovation—they are becoming the epicenter of outpatient surgical delivery.

34

Evolution to Revolution: Bacterial Vaginosis Testing & Treatment

A study, published in the New England Journal of Medicine (NEJM) on March 5th, 2025 has profoundly impacted our understanding of Bacterial vaginosis (BV).

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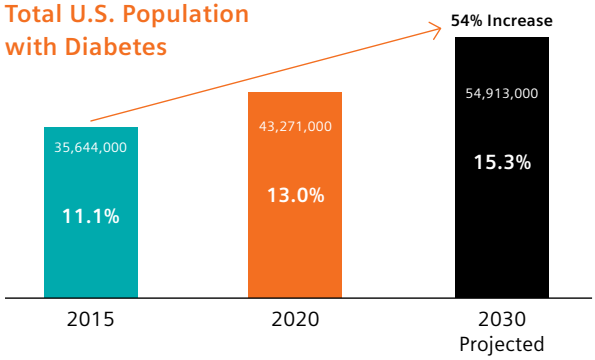
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Multiplex Testing at the Point of Care

BY AARON MEDARIS, PHYSICIANS OFFICE RESOURCE

Is it influenza, COVID, RSV, or some other respiratory infection? HCPs are faced with these questions every day as patients fill their exam rooms with coughs, fevers, and congestion. Your training and experience will help you in your diagnosis and subsequent treatment, but with so many similar symptoms between different infections, the need for assistance and even assurance is at an all-time high. Luckily, testing at the point of care is becoming more advanced and effective. One of the most important advancements in point of care testing is the addition of multiplex testing – the ability analyze multiple analytes or targets in a single test. Multiplex testing is nothing new but has been steadily evolving over the last several decades and is gaining a larger presence in physician offices and urgent care centers around the nation. In this article, take a closer look at multiplex testing, its development over the years, and how it's making a difference in point of care testing.

Understanding Multiplex Testing

Multiplex testing, also known as multiplexing or multiplex assay, is a technique used in laboratory diagnostics to simultaneously analyze multiple analytes or targets in a single test. It allows for the efficient and cost-effective detection of multiple biomarkers or genetic variants in a single sample.

Traditionally, diagnostic tests would focus on a single target, requiring separate tests for each analyte of interest. Multiplex testing revolutionizes this process by enabling the detection of multiple targets in a parallel and high-throughput manner.

There are different methods of multiplex testing, depending on the specific application and technology used. Here are a few examples:

- *Multiplex Polymerase Chain Reaction (PCR): PCR is a widely used technique to amplify and detect specific DNA sequences. Multiplex PCR involves designing primers that can amplify multiple target DNA sequences simultaneously. By incorporating different fluorescent dyes or molecular tags, the amplified products can be differentiated and detected in a single reaction.*

- *Multiplex Immunoassays: These assays are used to detect and quantify proteins or antibodies in a biological sample. Multiplex immunoassays employ different types of capture beads or microarrays, each coated with specific antibodies or antigens. By labeling the analytes with fluorescent or enzymatic tags, multiple targets can be detected and quantified simultaneously.*

- *Mass Spectrometry-based Multiplexing: Mass spectrometry can be used for multiplex analysis by labeling analytes with unique mass tags. By introducing stable isotopes or mass labels, multiple samples can be combined and analyzed together, allowing for the simultaneous detection of multiple targets.*

Multiplex testing offers several advantages over single-target assays, including reduced sample volume requirements, lower

costs, and faster turnaround time. It has found applications in various fields, including clinical diagnostics, infectious disease testing, genetic testing, and drug discovery.

The Evolution of Multiplex Testing

The concept of multiplex testing has been evolving over several decades, and the specific techniques used in multiplex testing have been developed and refined over time. Here are some key milestones in the history of multiplex testing:

- *1980s: The development of enzyme-linked immunosorbent assays (ELISAs) laid the foundation for multiplex immunoassays. ELISAs allowed for the quantification of a single analyte, but researchers began exploring ways to expand the assay to measure multiple targets simultaneously.*

- *1990s: Multiplex PCR techniques started to emerge during this period. Researchers began developing methods to amplify and detect multiple DNA targets using PCR, such as multiplex allele-specific PCR (AS-PCR) and multiplex ligation-dependent probe amplification (MLPA).*

- *Late 1990s to early 2000s: The advent of microarray technology revolutionized multiplex testing. DNA microarrays allowed for the simultaneous analysis of thousands of genetic targets. This technology enabled gene expression profiling, SNP genotyping, and other multiplex applications.*

- *2000s: The field of multiplex immunoassays expanded with the introduction of microsphere-based technologies. Luminex Corporation introduced the xMAP® (Multiplexed Assays with Beads) technology, which uses color-coded beads to enable the detection of multiple analytes simultaneously.*

- *2010s: Advances in next-generation sequencing (NGS) technologies facilitated high-throughput multiplex sequencing. Techniques such as targeted sequencing panels and amplicon sequencing allowed researchers to simultaneously analyze multiple genetic variants or mutations.*

These milestones illustrate the progressive development and application of multiplex testing techniques. The field continues to evolve, with ongoing advancements in technology, assay design, and data analysis methods, enabling even more comprehensive and efficient multiplex testing capabilities.

Multiplex Testing at the Point of Care

Multiplex testing at the point of care refers to the use of multiplex assays or devices in settings outside of a central laboratory, such as clinics, doctor's offices, or even at home. Point-of-care multiplex testing offers several advantages, including rapid results, immediate clinical decision-making, and improved patient management. Here are some examples of how multiplex testing is used at the point of care:

- **Infectious Disease Diagnosis:** *Multiplex assays are commonly used for the simultaneous detection of multiple pathogens in infectious disease diagnostics. Point-of-care multiplex tests can rapidly identify the presence of multiple viral, bacterial, or parasitic pathogens in a single sample, enabling timely diagnosis and appropriate treatment decisions. For example, a single test may detect respiratory viruses like influenza A and B, respiratory syncytial virus (RSV), and SARS-CoV-2 (the virus that causes COVID-19).*

- *Syndromic Panels: Syndromic panels combine multiplex testing with a broad range of targets related to specific clinical syndromes, such as respiratory infections, gastro intestinal infections, or sexually transmitted infections. These panels can simultaneously detect multiple pathogens associated with a particular syndrome, providing a comprehensive diagnostic approach and aiding in targeted treatment.*

- *Pharmacogenetics: Point-of-care multiplex testing can be utilized to analyze multiple genetic variants associated with drug metabolism or treatment response. These tests can provide insights into an individual's genetic profile and help guide personalized medication selection or dosing adjustments.*

- *Cancer Biomarkers: Multiplex assays can be used at the point of care to detect multiple cancer biomarkers, such as specific mutations or protein markers. These tests aid in cancer diagnosis, prognosis, and treatment decision-making, allowing for a more targeted and personalized approach.*

- *Rapid Screening: Multiplex tests can be employed for rapid screening of various conditions or diseases. For instance, multiplex lateral flow assays are commonly used for point-of-care testing of pregnancy, infectious diseases, cardiac markers, or drug testing. These tests provide quick results and are often simple to use, making them suitable for non-laboratory settings.*

Recent advancements even include CLIA Waived multiplex testing, allowing healthcare professionals to make immediate and informed decisions, leading to improved patient care and outcomes.

As of May 9, 2025, the Centers for Disease Control and Prevention (CDC) reports that there have been an estimated 226 pediatric influenza deaths in the United States during the 2024-2025 season. This is the highest number of pediatric deaths from the flu since the 2009-2010 season. The time to prepare for the next flu season is now. Have your diagnostic tests available now, before patients begin to fill your exam room with coughs, congestion, and fevers.

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2 ANS Testing

(can be combined with SUDOMOTOR into 1 full system)

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- Takes less than 10 minutes to perform, software provides verbal cues
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- **Reimburses $170/test using 3 CPT codes**
- Provides a 1 page summary up to a full 24 page comprehensive report



3 SudoMotor Testing

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- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
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OGSIVEO demonstrated significant improvements in PFS and ORR in the largest completed trial in adults with desmoid tumors[2,*]

- **71% reduction in the risk of disease progression or death** vs placebo (HR=0.29; 95% CI: 0.15, 0.55; *P*<0.001)[†]
  - Median PFS in the OGSIVEO arm was not reached (95% CI: NR, NR) compared with 15.1 months (95% CI: 8.4, NR) in the placebo arm[‡]
  - PFS events occurred in 12 patients (17%) in the OGSIVEO arm and 37 patients (51%) in the placebo arm
- **41% (95% CI: 29.8, 53.8; n=29) objective response rate** with OGSIVEO vs 8% (95% CI: 3.1, 17.3; n=6) with placebo; *P*<0.001[§,‖]
  - Complete response: 7% (n=5) with OGSIVEO vs 0% (n=0) with placebo
  - Partial response: 34% (n=24) with OGSIVEO vs 8% (n=6) with placebo
- PFS results were supported by change from baseline in **patient-reported worst pain intensity favoring the OGSIVEO arm[¶]**

The most common (≥15%) adverse reactions in patients receiving OGSIVEO in the DeFi study were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).[2]

DeFi Study Design: An international, multicenter, randomized, double-blind, placebo-controlled, Phase 3 trial of adult patients with progressing desmoid tumors (N=142). At study entry, all patients had histologically confirmed desmoid tumors that had progressed ≥20% by RECIST v1.1 within the past 12 months. Patients were either treatment-naïve with desmoid tumors not amenable to surgery or refractory/recurrent following at least one line of prior therapy. Patients were stratified according to the location of the target tumor (intra-abdominal vs extra-abdominal) and randomized 1:1 to receive 150 mg OGSIVEO (n=70) or placebo (n=72) orally twice daily until disease progression or unacceptable toxicity. Tumor imaging occurred every 3 months. The primary end point was progression-free survival. Key secondary efficacy end points included objective response rate and change from baseline at Cycle 10 in patient-reported worst pain intensity (Brief Pain Inventory-Short Form [BPI-SF]).[2,3]

*Completed double-blind, randomized, Phase 3 trial in adult patients with desmoid tumors.[2,3]

[†]Progression-free survival was defined as the time from randomization until the date of imaging-based or clinical progression or death. Progression-free survival was based on RECIST v1.1 as assessed by blinded independent central review or on clinical progression by the investigator (and confirmed by independent review). Clinical progression required worsening of symptoms resulting in a global deterioration of health status causing the permanent discontinuation from trial treatment and the initiation of emergent treatment (eg, radiotherapy, surgery, or systemic therapy including chemotherapy or tyrosine kinase inhibitors) for desmoid tumors. *P*-value was from a one-sided stratified log-rank test with placebo as reference.[2,3]

[‡]Data cut-off as of April 7, 2022 for PFS. Obtained using Kaplan-Meier methodology.[2,3]

[§]Objective response rate was defined as complete response or partial response according to RECIST v1.1. Assessed by blinded independent central review. Partial response was defined as a ≥30% decrease in the sum of the longest diameters of target tumors. Complete response was defined as disappearance of all target and non-target tumors. Obtained using exact method based on binomial distribution. *P*-value was from a two-sided Cochran-Mantel-Haenszel test.[2,3]

[‖]Desmoid tumors can have an unpredictable course and may exhibit spontaneous regression.[4]

[¶]Patient-reported worst pain intensity was assessed daily using item 3 of the BPI-SF, an 11-point numerical rating scale ranging from 0 ("no pain") to 10 ("pain as bad as you can imagine") and averaged over 7 days prior to each visit.[2,3]

CI, confidence interval; DeFi, Desmoid Fibromatosis; FDA, US Food and Drug Administration; HR, hazard ratio; NR, not reached; ORR, objective response rate; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors.

References: 1. Data on file. SpringWorks Therapeutics, Inc. Based on analysis of Veeva Compass claims data from February 1, 2024, through July 31, 2024. **2.** OGSIVEO. Prescribing Information. SpringWorks Therapeutics, Inc. **3.** Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a gamma-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388(10):898-912. **4.** Penel N, Chibon F, Salas S. Adult desmoid tumors: biology, management and ongoing trials. *Curr Opin Oncol*. 2017;29(4):268-274.

Ogsiveo®
(nirogacestat)
150 mg & 100 mg tablets

Indication

OGSIVEO is indicated for adult patients with progressing desmoid tumors who require systemic treatment.

Important Safety Information

Warnings and Precautions

Diarrhea: Diarrhea, sometimes severe, can occur in patients treated with OGSIVEO. Diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.

Ovarian Toxicity: Female reproductive function and fertility may be impaired in patients treated with OGSIVEO. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

Hepatotoxicity: ALT or AST elevations occurred in 30% and 33% of patients, respectively. Grade 3 ALT or AST elevations (>5 x ULN) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as recommended.

Non-Melanoma Skin Cancers: New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.

Electrolyte Abnormalities: Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate <2 mg/dL occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.

Embryo-Fetal Toxicity: OGSIVEO can cause fetal harm when administered to pregnant women. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and death at maternal exposures below human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

Adverse Reactions

The most common (≥15%) adverse reactions were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).

Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in ≥2% of patients were ovarian toxicity (4%).

The most common laboratory abnormalities (≥15%) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

Drug Interactions

CYP3A Inhibitors and Inducers: Avoid concomitant use with strong or moderate CYP3A inhibitors (including grapefruit products, Seville oranges, and starfruit) and strong or moderate CYP3A inducers.

Gastric Acid Reducing Agents: Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO can be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).

Consult the full Prescribing Information prior to and during treatment for important drug interactions.

Use in Specific Populations

Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

Please see brief summary of full Prescribing Information on subsequent pages.

Learn more and access resources at **OGSIVEO.com/hcp**

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use OGSIVEO safely and effectively. See full prescribing information for OGSIVEO.

OGSIVEO® (nirogacestat) tablets, for oral use

Initial U.S. Approval: 2023

INDICATIONS AND USAGE

OGSIVEO is indicated for adult patients with progressing desmoid tumors who require systemic treatment.

WARNINGS AND PRECAUTIONS

Diarrhea

Diarrhea, sometimes severe, can occur in patients treated with OGSIVEO.

In DeFi, diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event for patients treated with OGSIVEO was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.

Ovarian Toxicity

Female reproductive function and fertility may be impaired in patients being treated with OGSIVEO. Impact on fertility may depend on factors including the duration of therapy and the state of gonadal function at the time of treatment. The long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment with OGSIVEO. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

Hepatotoxicity

ALT or AST elevations occurred in 30% and 33% of patients who received OGSIVEO in DeFi, respectively. Grade 3 ALT or AST elevations (> 5 × ULN) occurred in 6% and 2.9% of patients, respectively. Monitor liver function tests regularly and modify dose as recommended.

Non-Melanoma Skin Cancers

New non-melanoma skin cancers can occur in patients treated with OGSIVEO. In DeFi, cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.

Electrolyte Abnormalities

Electrolyte abnormalities can occur in patients treated with OGSIVEO. In DeFi, these included decreased phosphate (65%) and decreased potassium (22%). Phosphate <2 mg/dL occurred in 20% of patients who received OGSIVEO. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.

Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, OGSIVEO can cause fetal harm when administered to pregnant women. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and death at maternal exposures below the human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

ADVERSE REACTIONS

Clinical Trials Experience

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

The safety of OGSIVEO was evaluated in 69 patients enrolled in DeFi with progressing desmoid tumor. Patients received OGSIVEO 150 mg orally twice daily or placebo orally twice daily until disease progression or unacceptable toxicity. The median duration of exposure to OGSIVEO was 20.6 months (range: 0.3 to 33.6).

Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in ≥ 2% of patients were ovarian toxicity (4%).

Permanent discontinuation of OGSIVEO due to an adverse reaction occurred in 20% of patients. Adverse reactions which resulted in permanent discontinuation of OGSIVEO in ≥ 2% of patients were diarrhea, ovarian toxicity, increased ALT, and increased AST.

Dosage interruptions of OGSIVEO due to an adverse reaction occurred in 51% of patients. Adverse reactions which required dosage interruption in ≥ 2% of patients included diarrhea, rash, stomatitis, hypophosphatemia, fatigue, folliculitis, nausea, and ovarian toxicity.

Dose reductions of OGSIVEO due to an adverse reaction occurred in 42% of patients. Adverse reactions which required dose reductions in ≥ 2% of patients included diarrhea, rash, stomatitis, hypophosphatemia, folliculitis, hidradenitis, and ovarian toxicity.

The most common (≥ 15% with a difference between arms of ≥ 5% compared to Placebo) adverse reactions that occurred in patients receiving OGSIVEO were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection and dyspnea.

Table 1 summarizes the adverse reactions that occurred in DeFi.

Table 1. Adverse Reactions (≥ 15%) in Patients with Desmoid Tumor Who Received OGSIVEO with a Difference Between Arms of ≥ 5% Compared to Placebo on DeFi

Adverse Reaction	OGSIVEO (N=69)		Placebo (N=72)	
	All Grades (%)	Grade 3 (%)	All Grades (%)	Grade 3 (%)
Gastrointestinal				
Diarrhea	84	16	35	1.4
Nausea	54	1.4	39	0
Stomatitis[a]	39	4	4	0
Abdominal Pain[a]	22	1.4	14	1.4
Reproductive System				
Ovarian toxicity[a,b]	75[c]	0	0	0
Skin and Subcutaneous Tissue				
Rash[a]	68	6	14	0
Alopecia	19	0	1.4	0
General				
Fatigue[a]	54	2.9	38	0
Nervous System				
Headache[a]	30	0	15	0
Respiratory				
Cough[a]	20	0	6	0
Dyspnea	16	0	6	0
Infections				
Upper respiratory tract infection[a]	17	0	2.8	0

[a]Includes multiple related composite terms

[b]Investigator assessment of ovarian toxicity included ovarian failure, premature menopause, amenorrhea, and menopause

[c]The number of females of reproductive potential in each arm is used as the denominator (OGSIVEO N = 36, Placebo N = 37)

Clinically relevant adverse reactions occurring in < 15% of patients receiving OGSIVEO in DeFi included non-melanoma skin cancers, epistaxis, hidradenitis suppurativa, folliculitis, and influenza-like illness.

Table 2 summarizes laboratory abnormalities in DeFi.

Table 2. Laboratory Abnormalities (≥ 15%) that Worsened from Baseline in Patients with Desmoid Tumor Who Received OGSIVEO in DeFi

Laboratory Abnormality	OGSIVEO		Placebo	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Chemistry				
Decreased phosphate[a,b]	65	Not Applicable	11	Not Applicable
Increased urine glucose[c,d]	51	Not Applicable	0	Not Applicable
Increased urine protein[c]	40	0	25	0

Laboratory Abnormality	OGSIVEO		Placebo	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Chemistry				
Increased aspartate aminotransferase[a]	33	2.9	18	1.4
Increased alanine aminotransferase[a]	30	6	21	1.4
Decreased potassium[a]	22	1.4	4.2	0

[a]The denominator used to calculate the rate was 69 for nirogacestat and 72 for placebo based on the number of patients with a baseline value and at least one post-treatment value.

[b]CTCAE Version 5.0 does not include numeric thresholds for grading of hypophosphatemia; all grades represent patients with lab value < Lower Limit of Normal (LLN).

[c]The denominator used to calculate the rate was 68 for nirogacestat and 69 for placebo based on the number of patients with a baseline value and at least one post-treatment value.

[d]CTCAE Version 5.0 does not include numeric thresholds for grading of increased urine glucose.

DRUG INTERACTIONS

Effects of Other Drugs on OGSIVEO

Table 3. Effects of Other Drugs on OGSIVEO

Strong or Moderate CYP3A Inhibitors	
Clinical Effect	Nirogacestat is a CYP3A substrate. Strong or moderate CYP3A inhibitors increase nirogacestat exposure, which may increase the risk of OGSIVEO adverse reactions.
Prevention or Management	Avoid concomitant use of OGSIVEO with strong or moderate CYP3A inhibitors including grapefruit products, Seville oranges, and starfruit.
Strong or Moderate CYP3A Inducers	
Clinical Effect	Nirogacestat is a CYP3A substrate. Strong or moderate CYP3A inducers decrease serum nirogacestat exposure, which may reduce the effectiveness of OGSIVEO.
Prevention or Management	Avoid concomitant use of OGSIVEO with strong or moderate CYP3A inducers.
Gastric Acid Reducing Agents	
Clinical Effect	Nirogacestat is poorly soluble at pH ≥ 6. Gastric acid reducing agents may decrease serum nirogacestat exposure, which may reduce the effectiveness of OGSIVEO.
Prevention or Management	Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO can be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).

Effects of OGSIVEO on Other Drugs

Table 4. Effects of OGSIVEO on Other Drugs

Certain CYP3A Substrates	
Clinical Effect	Nirogacestat increases exposure of CYP3A substrates, which may increase the risk of adverse reactions related to these substrates.
Prevention or Management	Avoid concomitant use with CYP3A substrates where minimal concentration changes may lead to serious adverse reactions.
Certain CYP2C19 Substrates	
Clinical Effect	Nirogacestat decreases exposure of CYP2C19 substrates, which may decrease efficacy of these substrates.
Prevention or Management	Avoid concomitant use with OGSIVEO where decreased concentrations of CYP2C19 substrates may lead to significant decreases in efficacy of the CYP2C19 substrate unless otherwise recommended in the Prescribing Information for the CYP2C19 substrate.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings from animal studies and its mechanism of action, OGSIVEO can cause fetal harm or loss of pregnancy when administered to a pregnant woman. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and embryo-fetal death at maternal exposures below the human exposure at the recommended dose of 150 mg twice daily [*see Data*].

There are no available data on the use of OGSIVEO in pregnant women. Advise pregnant women of the potential risk to a fetus.

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

Data

Animal Data

Daily oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in decreased fetal body weights, pre- and post-implantation loss, and fetal subcutis edema at doses ≥ 20 mg/kg/day (approximately 0.85 times the recommended dose of 150 mg twice daily based on area under the curve).

Lactation

Risk Summary

There are no data on the presence of nirogacestat or its metabolites in human milk or the effects of nirogacestat on a breastfed child or milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

Females and Males of Reproductive Potential

OGSIVEO can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating OGSIVEO.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

Males

Advise males with female partners of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

Infertility

Based on findings in animal studies, OGSIVEO can impair female and male fertility. OGSIVEO has been shown to interfere with folliculogenesis and spermatogenesis in nonclinical studies resulting in changes that included ovarian atrophy.

Pediatric Use

The safety and effectiveness of OGSIVEO have not been established in pediatric patients. Epiphyseal disorder, manifesting as a widening of the epiphyseal growth plate, has been reported in pediatric patients with open growth plates treated with OGSIVEO.

Geriatric Use

Of the total number of OGSIVEO-treated patients in the DeFi study, 3 (4%) were 65 years of age and older and none were 75 years of age and older. Clinical studies of OGSIVEO did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently than younger adult patients.

OVERDOSAGE

Due to the high level of protein binding, OGSIVEO is not expected to be dialyzable.

Manufactured for:
SpringWorks Therapeutics, Inc. Stamford, CT 06902

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The Global Future of Ambulatory Surgery Centers

BY: DR. SHAKEEL AHMED

"The future belongs to those who believe in the beauty of their dreams."
ELEANOR ROOSEVELT

Ambulatory Surgery Centers are no longer a peripheral innovation—they are becoming the epicenter of outpatient surgical delivery. In the United States and across both developed and emerging markets, ASCs are reshaping the economics, logistics, and ethics of surgical care.

United States: The U.S. ASC market was valued at $45.6 billion in 2024 and is projected to grow to $55.3 billion by 2029, marking a 21% increase. Outpatient surgical volumes are expected to reach 109.6 million cases by 2033—an 18% rise from 2023 levels.

Brazil: In 2023, Brazil's ASC market generated $1.46 billion in revenue, with projections reaching $2.2 billion by 2030. Orthopedics was the largest revenue-generating segment, while otolaryngology is anticipated to experience the fastest growth.

United Kingdom: The UK ASC market is expected to grow from $9.65 billion in 2023 to $14.59 billion by 2030, at a CAGR of 6.1%. Orthopedics leads in revenue, while otolaryngology is projected to grow the fastest.

Germany: Germany's ambulatory services market generated $73.56 billion in 2023 and is forecasted to reach $106.89 billion by 2030, growing at a CAGR of 5.5%. Surgical specialties are the fastest-growing segment, reflecting a shift toward outpatient surgical care.

In my opinion, these are the emerging trends that are transforming the outpatient surgery market and will define the future of ambulatory surgery centers.

Technological Renaissance in Outpatient Surgery

Over the last few decades, the evolution and improvement of technology have transformed surgery centers from simple procedural sites into hubs of medical innovation. Minimally invasive surgeries—including laparoscopic and arthroscopic procedures—are increasingly performed in outpatient settings. These are now paired with robotic-assisted systems and precision-guided imaging that enhance outcomes and minimize complications.

I have personally witnessed procedures once considered too complex for outpatient settings—such as total knee replacements, cervical fusions, and cardiac ablations—now performed routinely in ASCs across the country and internationally. This progress is due in large part to the rise of smarter operating rooms, featuring real-time intraoperative analytics, integrated artificial intelligence diagnostic systems, and advanced surgical tools.

Globally, this adoption is accelerating. Countries like Singapore and Germany are rapidly implementing intelligent surgical platforms, often retrofitting existing facilities to meet new standards. According to GlobalData, over 70% of new ASC constructions in the U.S. by 2028 will be equipped with robotic capabilities. As this renaissance continues, surgery centers are not merely viable alternatives—they are becoming the rightful and ethical frontrunners of surgical care.

Unmatched Cost Efficiency and Economic Sustainability

Since their inception, ASCs have stood as pillars of cost containment in surgical care—a truth that is more evident today than ever before. National data shows that, on average, procedures performed in ASCs are 45% less expensive than the same procedures conducted in hospital outpatient departments.

From experience, I can attest that this advantage stems from streamlined infrastructure, lower administrative overhead, and focused workflows. For example, Medicare pays nearly $1,000 less for cataract surgery when performed in an ASC versus a hospital. The same cost efficiencies apply to colonoscopies and knee procedures. These savings extend to insurers, patients, and the healthcare system at large.

ASCs also boast higher procedural turnover, enabling more cases to be performed per day with fewer resources. In bundled payment models and Accountable Care Organizations (ACOs), ASCs have been shown to reduce total episode costs by up to 30%. Increasingly, employers are directing their workforces toward ASC networks as a strategy to control self-funded healthcare costs. With national healthcare spending projected to reach 20% of U.S. GDP by 2028, ASCs represent a sustainable solution for both public and private payers.

The Consumerization of Surgery and Patient-Driven Design

Modern surgical patients expect more than clinical competence—they demand convenience, cost transparency, personalization, and a premium experience. ASCs have responded accordingly, blending luxury hospitality with medical excellence.

Digital preoperative platforms now allow patients to complete paperwork and medication reconciliation from home. Real-time procedure tracking systems keep families informed, while post-discharge apps monitor pain scores and wound healing—tools I've highlighted in previous writings. Millennials and Gen X, now the dominant cohort for elective procedures, overwhelmingly prefer ASCs due to lower infection risks, shorter wait times, and more personalized care.

According to Press Ganey, patient satisfaction in ASCs averages 92%, compared to 84% in hospital surgical units. Many ASCs now offer concierge services and direct-pay pricing for uninsured and international patients. As healthcare becomes more of a competitive service industry, ASCs are setting the gold standard by merging clinical outcomes with consumer convenience.

Policy Tailwinds Accelerating Global ASC Adoption

Governments worldwide are increasingly endorsing outpatient surgical models as a means to reduce healthcare costs and address surgical backlogs. In the United States, the Centers for Medicare & Medicaid Services (CMS) has added over 60 procedures to its ASC-covered list in the past five years, including total knee arthroplasty and cardiac ablation.

In the United Kingdom, Independent Sector Treatment Centers (ISTCs) now account for over 8% of elective procedures, easing strain on NHS hospitals. Germany's Federal Joint Committee (G-BA) has expanded outpatient allowances, mandating a shift from hospitals to specialized day clinics. Middle-income countries such as Brazil and Mexico are promoting ASCs through public-private partnerships.

The World Health Organization has identified outpatient expansion as a strategic pillar in global surgical reform. A collective policy shift is underway: ASCs are being institutionalized not as fringe alternatives, but as core components of modern healthcare infrastructure.

Here is the continuation of the fully corrected and professionally formatted article — Sections 5 through 12:

Physician Autonomy and Ownership-Driven Innovation

One of the most compelling aspects of the ASC model is its ownership structure. Nearly 65% of ASCs in the U.S. are partially or fully physician-owned, according to VMG Health. I have seen firsthand how this structure aligns clinical and operational goals in ways that large hospital systems cannot replicate.

Physician-owners are more likely to invest in advanced technologies, eliminate unnecessary testing, and adhere to evidence-based protocols. A study published in Health Affairs found that physician-owned ASCs had a 17% lower complication rate for common orthopedic procedures compared to hospital-based surgical departments.

Globally, countries like Kenya and Colombia are witnessing a rise in physician-founded ASCs, as local doctors seek independence from bureaucratic systems. In Brazil, orthopedic specialists have formed regional ASC cooperatives to pool resources and scale their outpatient services. The ASC business model fosters a culture of innovation, initiative, and agility—qualities essential to modern, high-stakes healthcare environments.

Private Equity and Strategic Capital Infusion

A frequent question I receive is about the biggest financial transformation in outpatient surgery over the last decade. In my view, the answer is unequivocal: private equity. Between 2019 and 2023, private equity transactions involving ASCs more than doubled, with over 150 acquisitions in 2023 alone, according to PitchBook.

This influx of capital has accelerated growth. Multi-site chains are consolidating under regional brands, new centers are sprouting in underserved markets, and specialty-focused ASCs—particularly in GI, spine, and orthopedics—are attracting aggressive investments. In the UK, private equity is targeting ophthalmology ASCs to meet rising cataract surgery demands, projected to grow 25% by 2030.

However, the PE model is not without controversy. Critics, myself included, worry that investor-driven operations may prioritize volume over value, pressuring providers to work at unsafe speeds. That said, there are undeniable advantages: private equity enables the deployment of advanced revenue cycle systems, AI-based scheduling tools, and real estate strategies that would be out of reach for smaller physician groups. This relationship between private capital and ASC expansion will continue to define how outpatient surgery is financed and delivered in the future.

Outpatient Growth in Emerging Economies

Emerging markets have become unexpected leaders in ASC development. Countries like Brazil, Turkey, and South Africa are seeing explosive growth in outpatient surgery, driven by rising demand, limited hospital infrastructure, and younger demographics that favor convenience.

In Brazil, the ASC market is growing at 7.8% annually and is projected to reach $2.2 billion by 2030, with orthopedics and ophthalmology leading the way. These nations are leapfrogging traditional hospital models, opting instead for more affordable, tech-enabled outpatient solutions.

Governments are supporting the shift with tax incentives, public-private partnerships, and regulatory reform. I've visited several modern ASC facilities in these regions—equipped with modular ORs, mobile diagnostics, and AI-driven intake systems—and have found them not only expanding access, but also redefining global outpatient care standards.

Artificial Intelligence and Predictive Workflow Optimization

"Quality means doing it right when no one is looking."
— Henry Ford

There was a time when artificial intelligence (AI) was the stuff of science fiction. Today, it is actively reshaping ASC operations. At our centers, AI tools now optimize OR block times by analyzing case trends, durations, and staffing patterns—reducing downtime by 25–30%.

Predictive analytics helps flag high-risk patients for cancellation or complications, allowing staff to intervene proactively. Machine learning is also improving clinical care by predicting postoperative complications like infections or DVTs. Integrated triage systems powered by AI have improved surgical outcomes by up to 20% and reduced postoperative ER visits by 15%.

Remote monitoring tools track patient recovery in real-time and alert nurses to concerning trends—dramatically reducing admission rates. Globally, countries like Germany, South Korea, and the Netherlands are investing heavily in outpatient AI infrastructure. Deloitte projects that over 50% of high-volume ASCs in developed markets will implement clinical AI systems by 2028. This marks a turning point in the precision and personalization of surgical care.

Site-Neutral Payment Reform and Reimbursement Shifts

As an advocate for the ASC sector, I frequently emphasize the need for site-neutral payment reform—one of the most crucial

policy changes in U.S. healthcare. This reform would mandate equal reimbursement rates for identical procedures performed in ASCs and hospital outpatient departments (HOPDs). Currently, HOPDs are reimbursed up to 200% more than ASCs for the same surgeries.

CMS and MedPAC both endorse site-neutrality, with potential Medicare savings estimated at over $15 billion per decade. A RAND study found that diverting just 50% of eligible HOPD cases to ASCs could save the U.S. system $38 billion annually.

Globally, countries like Australia and Sweden are evaluating similar reforms to align cost incentives with outcomes. For our industry, site-neutrality represents not just fiscal justice—it is a structural inflection point that could catapult ASCs into market dominance.

Clinical Specialization and High-Acuity Capability

When I began in this field, ASCs were largely limited to low-risk procedures like cataracts and colonoscopies. Today, they routinely handle complex cases such as total joint replacements, multi-level spinal fusions, and even same-day cardiac ablations.

This transformation is driven by safer anesthesia protocols, better preoperative risk stratification, and increasingly sophisticated surgical equipment. A study in JAMA Surgery found that joint replacement outcomes in ASCs are equivalent—or even superior—to hospital settings, with fewer complications and faster recovery.

In Europe, countries like Sweden and Germany have certified orthopedic- and spine-focused ASCs that use regional anesthesia, ERAS (Enhanced Recovery After Surgery) protocols, and integrated pain management. The U.S. now has over 600 ASCs performing total joints, up from just 25 in 2014. As this specialization intensifies, ASC networks are evolving into centers of excellence, with higher quality control, better outcomes, and more efficient delivery models.

Digital Transformation and Virtual-First Integration

Digital transformation is revolutionizing ASC scalability and patient engagement. What started as a pandemic-era necessity has become permanent: telemedicine is now standard in preoperative consults, eliminating unnecessary in-person visits.

AI-enhanced scheduling platforms predict patient flow and staff needs, reducing surgical bottlenecks. Postoperative care is increasingly app-based, tracking pain, movement, and wound healing. A study in The American Journal of Surgery reported a 23% drop in 30-day complications when using such tools.

Billing and revenue cycle management have moved to the cloud, enabling real-time benefit verification, automated authorizations, and fewer denials. Countries like Singapore and the Netherlands are leading virtual-first ASC integration, using national EHRs to unify surgical workflows. This ecosystem is creating a model where outcomes, satisfaction, and efficiency reinforce one another.

Global Talent and Surgical Workforce Redistribution

The expansion of ASCs is reshaping not only care delivery but also workforce dynamics. Traditional hospital employment models are increasingly seen as rigid and burnout-inducing. ASCs offer greater autonomy, better income per hour, and more predictable schedules.

According to a 2023 Medscape survey, 63% of surgeons under age 45 would prefer to work in ASCs full-time. In Brazil and Colombia, younger surgeons are forming ASC cooperatives to exit bloated state-run systems. In the UK, private ASCs are recruiting NHS-trained specialists for flexible, consultant-based roles.

This model is also drawing talent in nursing, IT, and operations—attracted by mission-driven, agile environments. This workforce shift is about more than job satisfaction; it's about creating a care culture rooted in flexibility, professionalism, and purpose.

Conclusion

As surgical care evolves globally, Ambulatory Surgery Centers are emerging as the strategic nucleus of efficiency, innovation, and patient-centered delivery. What began as a cost-saving alternative has now become a cornerstone of 21st-century medicine.

From AI and robotics to policy reform and physician-led entrepreneurship, ASCs are not just transforming where surgery happens—but how it happens. Their model is scalable, sustainable, and indispensable. The message is clear: the ASC is no longer a substitute—it is the surgical institution of the future.

I end with the wise words of George Bernard Shaw, " Progress is impossible without change, and those who cannot change their minds cannot change anything."

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.



FOR ADULTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS (UC) OR CROHN'S DISEASE (CD)

THEIR UC AND CD GOALS ARE IN REACH. AND SO ARE YOURS WITH OMVOH.

Learn more about Omvoh by visiting **omvoh.lilly.com/hcp**



INDICATIONS AND IMPORTANT SAFETY INFORMATION

Omvoh is an IL-23p19 antagonist **indicated** for adults with moderately to severely active ulcerative colitis (UC) or moderately to severely active Crohn's disease (CD).

IMPORTANT SAFETY INFORMATION for Omvoh (mirikizumab-mrkz)

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 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

See additional Important Safety Information on next page.



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 druginduced 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 associated with Omvoh (≥2% of subjects and at a higher frequency than placebo) in ulcerative colitis treatment are upper respiratory tract infections and arthralgia during the induction study (UC-1), and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during the maintenance study (UC-2).

Most common adverse reactions associated with Omvoh in the Crohn's disease study (CD-1) (≥5% of subjects and at a higher frequency than placebo) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Omvoh injection is available as a 300 mg/15 mL solution in a single-dose vial for intravenous infusion, and as a 100 mg/mL solution or a 200 mg/2 mL solution in a single dose prefilled pen or prefilled syringe for subcutaneous injection. Refer to the Prescribing Information for dosing information.

MR HCP ISI CD APP

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

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Lilly
A MEDICINE COMPANY

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
- moderately to severely active Crohn's disease 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 pruritus, 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. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. 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.

Ulcerative Colitis

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.

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.

See Brief Summary of Prescribing Information on adjacent page.

Omvoh® (mirikizumab-mrkz) injection,
for intravenous or subcutaneous use MR HCP BS CD APP

[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]*.

Crohn's Disease
Omvoh was studied up to 52 weeks in subjects with moderately to severely active Crohn's disease in a randomized, double-blind, placebo-controlled study (CD-1). The safety population consisted of 630 subjects who received Omvoh 900 mg administered as an intravenous infusion during induction at Weeks 0, 4, and 8 followed by Omvoh 300 mg administered as a subcutaneous injection every 4 weeks and 211 subjects who received placebo. Eighty-five of the 211 placebo subjects in the safety population who did not achieve clinical response by patient- reported outcome at Week 12 were switched to blinded induction and maintenance treatment with Omvoh. Observed data from these 85 subjects are included in the placebo cohort up to Week 12 and in the Omvoh cohort after Week 12. In CD-1, Omvoh and placebo-treated subjects had different lengths of exposure, therefore, exposure adjusted incidence rates (EAIRs) are also displayed in Table 3 to compare adverse reactions.

Common Adverse Reactions
Table 3 summarizes the frequencies and EAIRs per 100 person-years (PY) for adverse reactions reported in at least 5% of subjects treated with OMVOH and at a higher frequency than placebo during CD-1.

Table 3: Adverse Reactions[a] in Subjects with Crohn's Disease through Week 52 In a Placebo-Controlled Study (CD-1)

Adverse Reactions	Omvoh[b] N=715, PY=655 n (%) [EAIR[c]]	Placebo N=211, PY=120 n (%) [EAIR[c]]
Upper respiratory tract infections[d]	199 (28) [37]	47 (22) [47]
Injection site reactions[e]	69 (10) [11]	8 (4) [7]
Headache[f]	45 (6) [7]	9 (4) [8]
Arthalgia	44 (6) [7]	11 (5) [10]
Elevated liver tests[g]	36 (5) [6]	8 (4) [7]

Abbreviations: EAIR, exposure-adjusted incidence rate; PY, person-years

[a] Reported in at least 5% of subjects and at a higher frequency than placebo.
[b] Following Omvoh 900 mg as an intravenous infusion at Week 0, Week 4, and Week 8, subjects received Omvoh 300 mg as a subcutaneous injection at Week 12 and every 4 weeks thereafter for up to an additional 40 weeks. In addition, eighty- five placebo subjects who did not achieve clinical response by patient-reported outcome at Week 12 were switched to blinded induction and maintenance treatment with Omvoh. The observed data after Week 12 from these eighty-five subjects were included in the Omvoh cohort.
[c] EAIRs are per 100 PY. The EAIR per 100 PY can be interpreted as an estimated number of first occurrences of the adverse reaction of interest if 100 subjects were treated for one year.
[d] Upper respiratory tract infections includes related terms (e.g., COVID-19, nasopharyngitis, pharyngitis, rhinitis, sinusitis, and upper respiratory tract infection).
[e] Injection site reactions includes related terms (e.g., erythema, hematoma, induration, pain, pruritus, and reaction at the injection site).
[f] Headache includes related terms (i.e., headache and migraine).
[g] Elevated liver tests include related terms (e.g., ALT increased, AST increased, alkaline phosphatase increased, bilirubin increased, and GGT increased).

Hepatic Enzyme Elevations
Of the subjects with reported adverse reactions of elevated liver tests (see Table 3), 3 subjects treated with Omvoh reported ALT ≥5X ULN and 2 subjects reported AST ≥5X ULN. Neither subject had a concomitant elevation in total bilirubin. No subjects treated with placebo experienced similar elevations.

Less Common Adverse Reactions (<5%)
In CD-1 through Week 52, urticaria was reported by 13 (2%, 2 per 100 PY) subjects treated with Omvoh and no subjects treated with placebo.

Infections
In CD-1 through Week 52, infections were reported by 282 (39%, 58 per 100 PY) subjects treated with Omvoh and 73 (35%, 81 per 100 PY) subjects treated with placebo. Serious infections in the Omvoh group included abscess (including abdominal abscess, anal abscess, gluteal abscess, and perineal abscess), cellulitis, pneumonia, and sepsis.

DRUG INTERACTIONS

CYP450 Substrates
Increased concentrations of cytokines (e.g., IL-1, IL-6, IL-10, TNFα, IFN) during chronic inflammation associated with certain diseases including Crohn's disease may suppress the formation of CYP450 enzymes. Therapeutic proteins, including mirikizumab-mrkz, that decrease the concentrations of these pro-inflammatory cytokines may increase the formation of CYP450 enzymes resulting in decreased CYP450 substrate exposure. Upon initiation or discontinuation of Omvoh in patients treated with concomitant CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP450 substrate as needed. See the prescribing information of specific CY450 substrates.

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 20 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.

See Brief Summary of Prescribing Information on adjacent page.

Omvoh® (mirikizumab-mrkz) injection,
for intravenous or subcutaneous use MR HCP BS CD APP

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. It is unclear whether mirikizumab-mrkz may interfere with an infant's immune response to infections. Therefore, monitoring for the development of serious infection during the first 2 months of life in infants exposed in utero is recommended.

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 (20 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 (20 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 ulcerative colitis 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 information in USPI]*.

Clinical studies of Omvoh for the treatment of Crohn's disease did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger adult 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 information in USPI]*.

DOSING

Recommended Dosage for Ulcerative Colitis

Induction Dosage:

Week 0, Week 4, and Week 8: Infuse 300 mg intravenously over at least 30 minutes. A full induction dose requires 1 Omvoh vial containing 300 mg/15 mL solution.

Maintenance Dosage:

Week 12 and every 4 weeks thereafter: Inject 200 mg subcutaneously (given as two consecutive injections of 100 mg each).

Recommended Dosage for Crohn's Disease

Induction Dosage:

Week 0, Week 4, and Week 8: Infuse 900 mg intravenously over at least 90 minutes. A full induction dose requires 3 Omvoh vials containing 300 mg/15 mL solution.

Maintenance Dosage:

Week 12 and every 4 weeks thereafter: Inject 300 mg subcutaneously (given as two consecutive injections of 100 mg and 200 mg in any order).

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 or syringe disposal.

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

Instruct Crohn's disease patients or caregivers to administer a 100 mg prefilled pen or prefilled syringe and a 200 mg prefilled pen or prefilled syringe in any order to achieve the full 300 mg dose of Omvoh.

Important Administration Instructions

The 200 mg/2 mL prefilled pen and prefilled syringe are only for maintenance treatment of Crohn's disease.

MR HCP BS CD APP

Additional information can be found at www.Omvoh.lilly.com. Call the Lilly Answers Center at 1-800-LillyRx (1-800-545-5979)

See Instructions for Use accompanying the product device.

PP-MR-US-1074

Omvoh® (mirikizumab-mrkz) injection,
for intravenous or subcutaneous use MR HCP BS CD APP

ABI

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- PAD symptoms are often mistaken for arthritis or old age.

The simpleABI Cuff-Link System is Easy to Learn and Use.
- With a push-button remote, automatic calculations, and waveforms, it's incredibly user-friendly.
- Reports are straightforward to save and share since the system is PC-based.

Outstanding Value and Reimbursements
- The system pays for itself in less than a year with just one test per week.
- Medicare reimbursements vary by exam and location, averaging from $91 to $174.



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Lightweight and pocket-sized, Bindex allows patients to receive on-the-spot bone density scans in doctors' offices, hospitals and clinics and at home.



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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



NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

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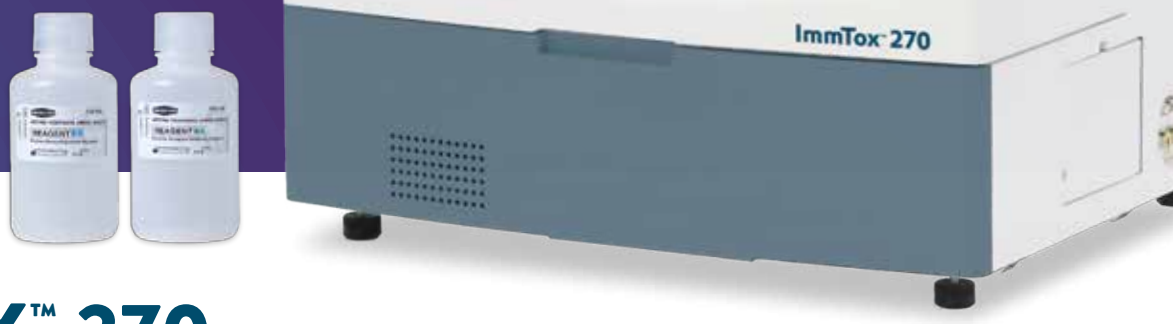
The U.S. FDA has cleared Nova Primary as a blood glucose reference analyzer that fills the need for a new reference analyzer to replace the YSI STAT PLUS 2300 (YSI, Inc., Yellow Springs, OH). Manufacturers of blood glucose measuring devices and clinical diabetes researchers have relied on the YSI 2300 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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Buprenorphine	Phencyclidine (PCP)
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1. Clinical Laboratory Improvement Amendments (CLIA) / * SEFRIA Fentanyl

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9 TRAVEL DESTINATIONS YOU CAN'T MISS IN 2025

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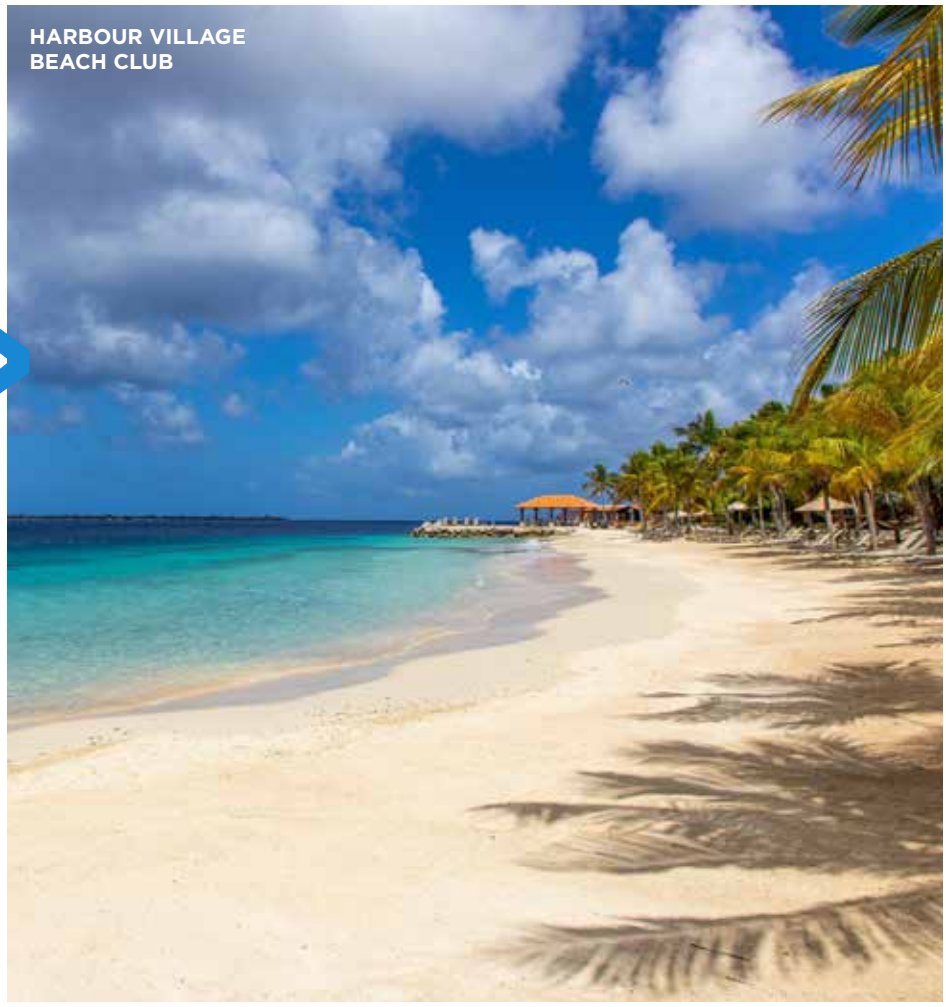
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Tucked away on a private stretch of white sand and palm trees, you will find the iconic Harbour Village Beach Club. An oasis beloved by sun lovers, scuba divers, and seafarers alike. Our boutique Bonaire retreat captures the breezy, barefoot elegance of the Dutch Caribbean, consistently earning the title of “Bonaire's leading hotel” in the World Travel Awards.

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TURTLE BAY RESORT

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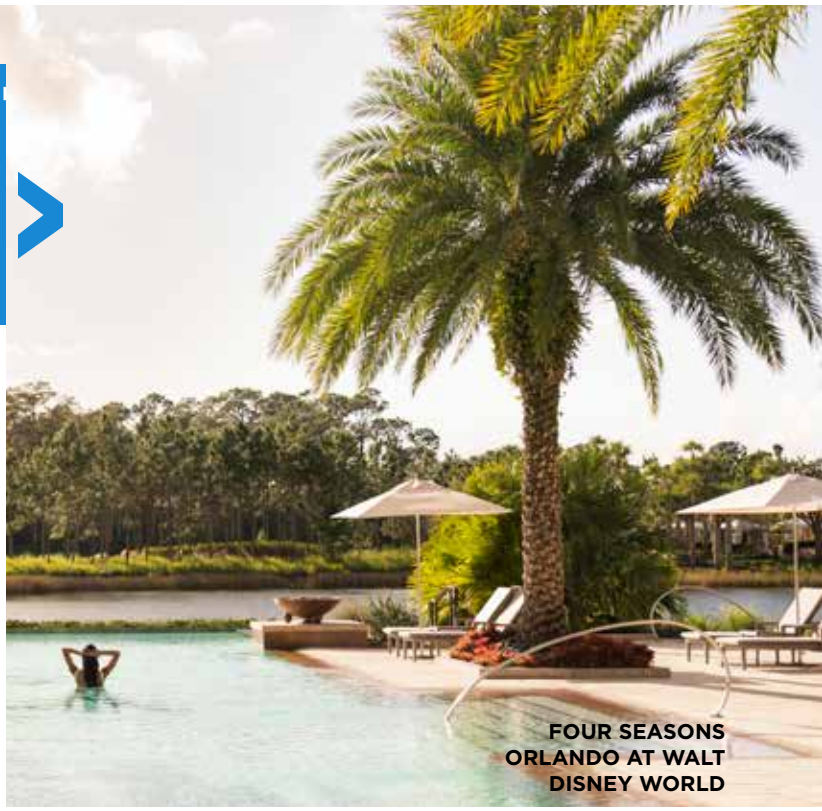
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NEWPORT BEACH , CALIFORNIA

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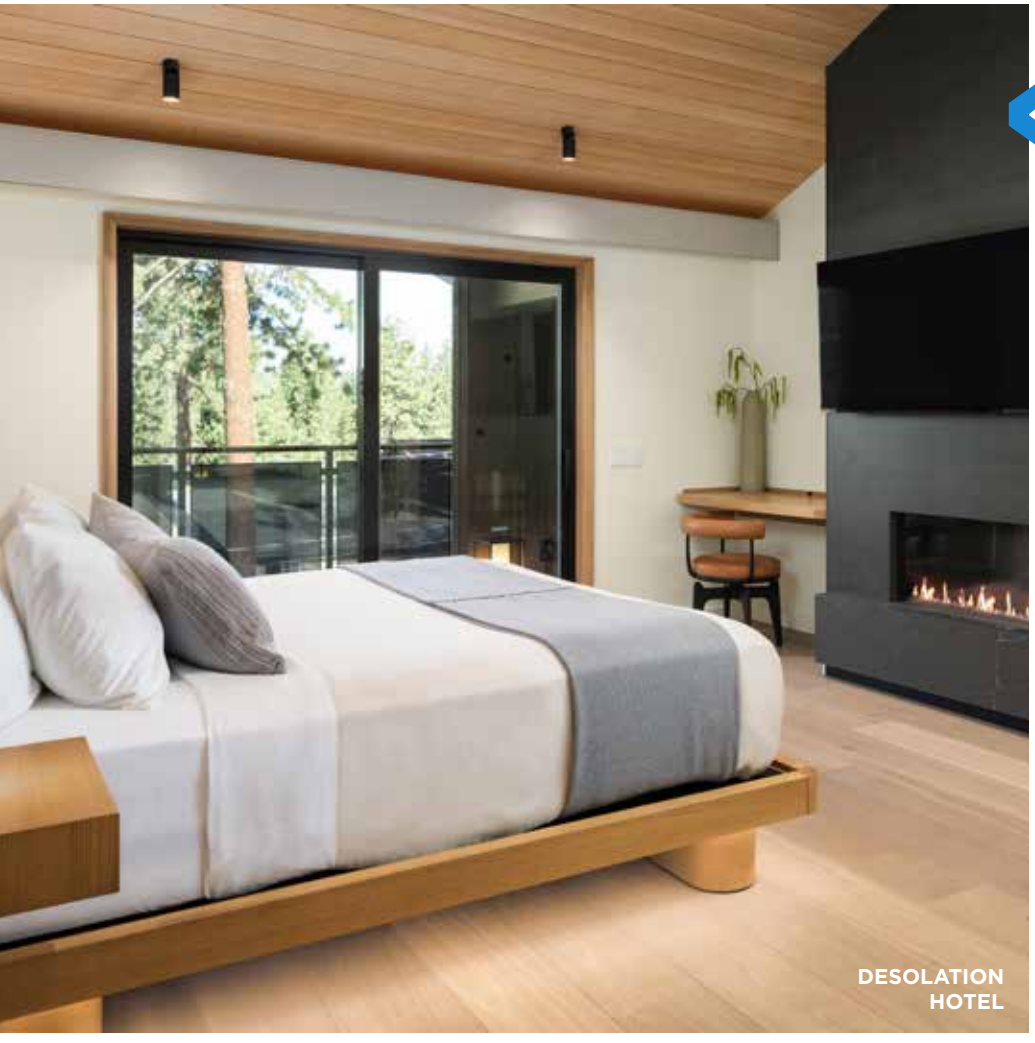
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TURTLE BAY RESORT

DESOLATION HOTEL

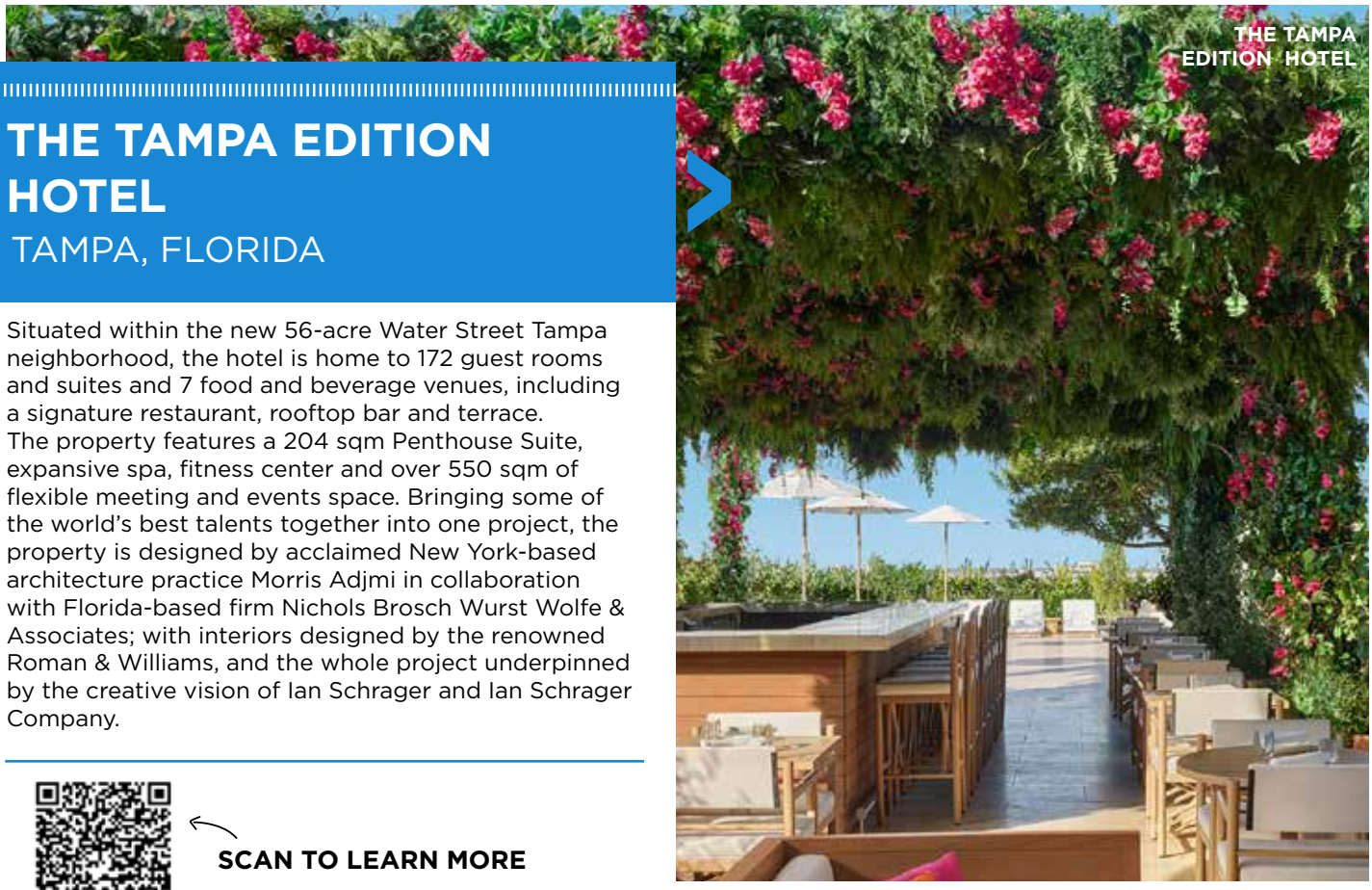
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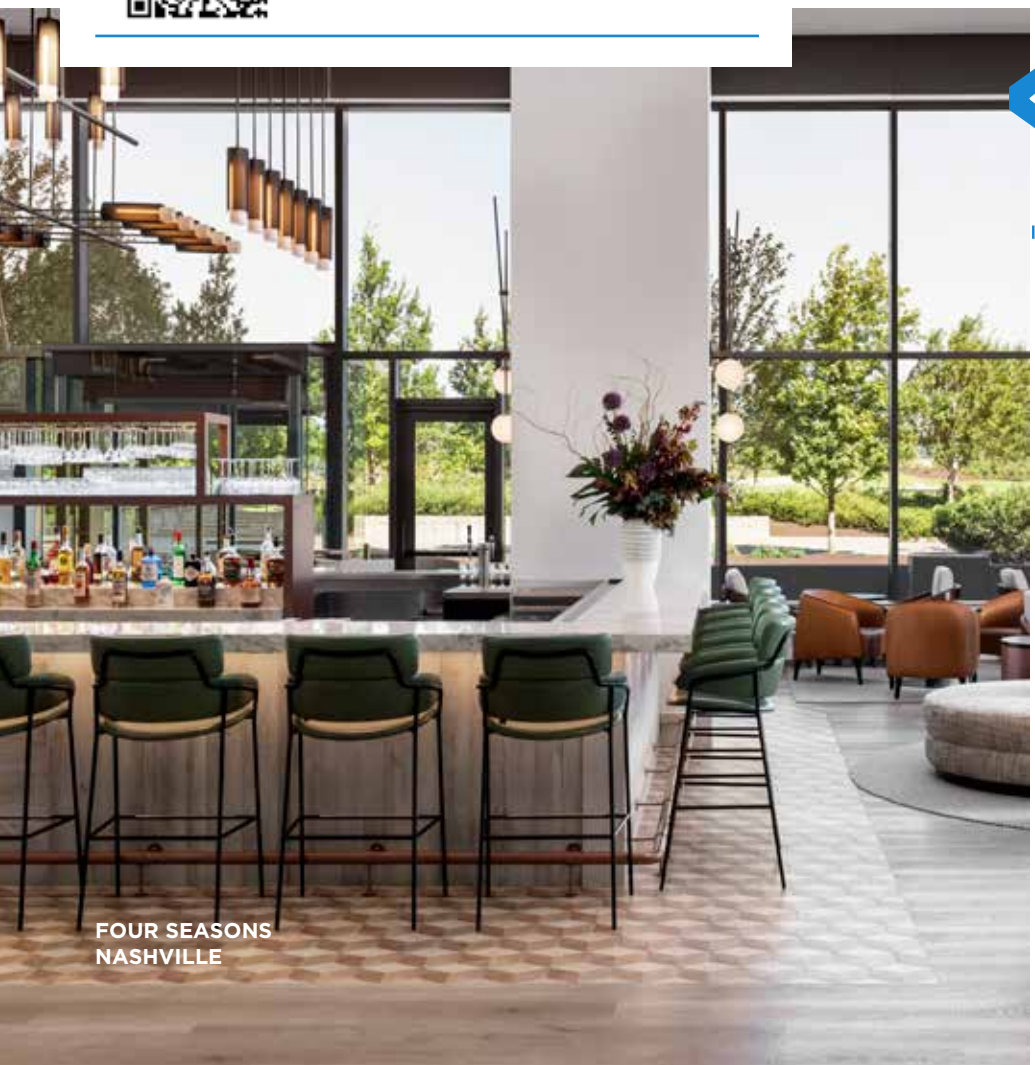
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THE TAMPA EDITION HOTEL

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FOUR SEASONS

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EVOLUTION TO REVOLUTION:

Bacterial Vaginosis Testing & Treatment

BY JEFF REID AND GALIT GELMAN, SEKISUI DIAGNOSTICS

A landmark study, Male-Partner Treatment to Prevent Recurrence of Bacterial Vaginosis, published in the New England Journal of Medicine (NEJM) on March 5th, 2025 has profoundly impacted our understanding of Bacterial vaginosis (BV), a condition affecting nearly a third of women worldwide.[1,2] This research, conducted in Melbourne Australia, reveals that BV is likely a Sexually Transmitted Infection (STI), challenging the long-held belief that it results from an imbalance in the vaginal microbiome and considered a common vaginal disorder. The findings have significant implications, and the medical community is now questioning how we approach BV testing and treatment, necessitating a shift towards a more comprehensive and inclusive diagnostic and therapeutic strategy.

Current Diagnostic Methods

Previously, BV diagnosis relied on clinical criteria, such as Amsel's Criteria, or determining the Nugent score from a vaginal Gram stain.[3] These methods involve assessing symptoms such as vaginal discharge, odor, and pH levels, as well as microscopic examination of vaginal smears for specific bacterial patterns. However, more modern and convenient methodologies for diagnosing BV have become available over the past decade. A prime example is the OSOM® BVBLUE® Test, which is a visual read enzymatic assay that detects sialidase activity in only 10 minutes.[4] This rapid, CLIA-waived test is designed for point-of-care testing, empowering healthcare professionals with the ability to test-&-treat at the very first patient visit. Also, there are molecular platforms available, such as the BD Max Vaginal Panel, that can accurately diagnose BV in a lab-based setting.[5]

While there are several effective tools and protocols diagnosing BV in females, there are no established diagnostic tests specifically for BV in males or a general test for both sexes. Current detection-in-males research focuses on detecting BV-associated bacteria in penile skin and urethral samples, but these methods are not widely available or standardized.[6]

The Melbourne Study

The Melbourne study, led by Professor Catriona Bradshaw and Dr. Lenka Vodstrcil, demonstrates that treating both partners simultaneously significantly reduces BV recurrence rates. In their trial involving 164 heterosexual, monogamous couples, the recurrence of BV was halved when both the female and her male partner received treatment compared to treating the female alone.[7] This breakthrough suggests that reinfection from sexual partners is a major factor in BV recurrence, supporting the notion that BV is indeed an STI.

Implications for Testing and Treatment: A Paradigm Shift

Given the new evidence, testing for BV should evolve to include considerations for sexual transmission. Here are several key changes that could enhance diagnostic accuracy and treatment efficacy:



1. Diagnostic Accuracy:

- **Point-of-Care Tests:** Tools like the OSOM® BVBLUE® Test continues to offer a rapid, affordable and reliable solution, which could be particularly beneficial in settings with limited laboratory resources or to patients experience reoccurrence of symptoms.[9] Affordable diagnostic tools are especially important if BV is added into national and inter national guidelines for routine STI screening.

- **PCR Testing:** While more expensive, polymerase chain reaction (PCR) tests can identify specific bacterial genetic material, potentially improving diagnostic accuracy. These tests could be used more widely, especially in cases where traditional methods are inconclusive.[3]

2. Inclusion of Sexual Partners in Testing and Treatment Protocols:

- **Testing for Male Partners:** Developing tests to detect BV-associated bacteria in males could help identify carriers and prevent reinfection. This would involve analyzing penile skin and urethral samples for bacteria linked to BV. [6]

- **Partner Treatment:** Incorporating partner treatment into standard care could significantly reduce recurrence rates. This involves administering oral and topical antibiotics to male partners simultaneously with female treatment.[8]

Challenges and Future Directions

While the Melbourne study offers promising insights, several challenges remain:

1. Stigma Associated with STIs: Labeling BV as an STI may increase stigma, requiring healthcare providers to approach discussions sensitively and emphasize the importance of partner involvement in treatment.[12]

2. Further Research Needs:

- **Diverse Populations:** Studies should be conducted in diverse populations, including non-monogamous relationships and LGBTQIA+ communities, to ensure that treatment strategies are universally effective.[13]

- **Bacterial Identification:** Identifying the specific bacteria responsible for BV could lead to more targeted treatments and diagnostic tests.[14]

3. Guideline Updates:

- Educating both healthcare providers and the public about BV as an STI is crucial. This includes discussing the role of sexual transmission and the importance of partner treatment to reduce stigma and improve treatment adherence.

- National and international health guidelines should be revised to reflect BV's status as an STI and recommend partner treatment. This will require coordination among health organizations and policymakers.

• Adding BV testing into the routine screening protocol when testing for STI's to reduce transmission and spread of the infection. As of now the CDC STI Treatment Guide lines list 9 of the most prevalent STIs, screening recommendations and treatment considerations.[15]

Conclusion

The Melbourne study marks a significant turning point in our understanding and management of BV. By acknowledging BV as a STI and incorporating it into standard screening and treatment as well as providing partner treatment into standard care, we can improve cure rates and reduce recurrence. However, this shift requires a multifaceted approach, including enhanced diagnostic tools, public education, and further research to address the complexities of sexual transmission. As we move forward, it is essential to balance the need for effective treatment with sensitivity towards the stigma associated with STIs, ensuring that all individuals affected by BV receive comprehensive and compassionate care.

Citations

1. Vodstrcil LA, Plummer EL, Doyle M, et al. Treating male partners of women with bacterial vaginosis (StepUp): a protocol for a randomised controlled trial to assess the clinical effectiveness of male partner treatment for reducing the risk of BV recurrence. BMC Infect Dis. 2020;20(1):834. Published 2020 Nov 11. doi:10.1186/s12879-020-05563-w

2. New STI impacts 1 in 3 women: landmark study reveals men are the missing link. Medicine, Nursing and Health Sciences. Published March 28, 2025. https://www.monash.edu/medicine/news/latest/2025-articles/new-sti-impacts-1-in-3-women-landmark-study-reveals-men-are-the-missing-link

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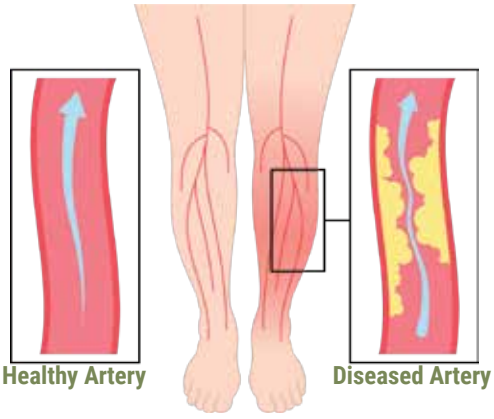
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