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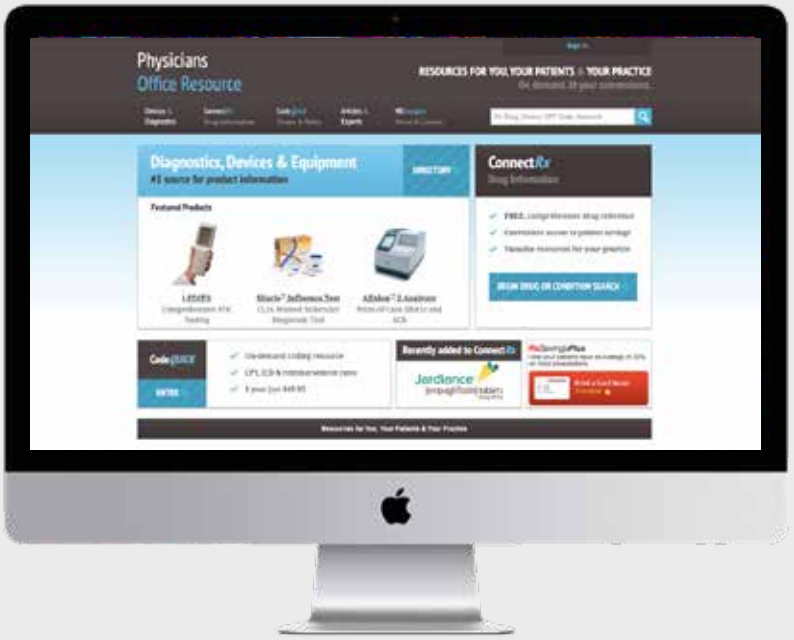
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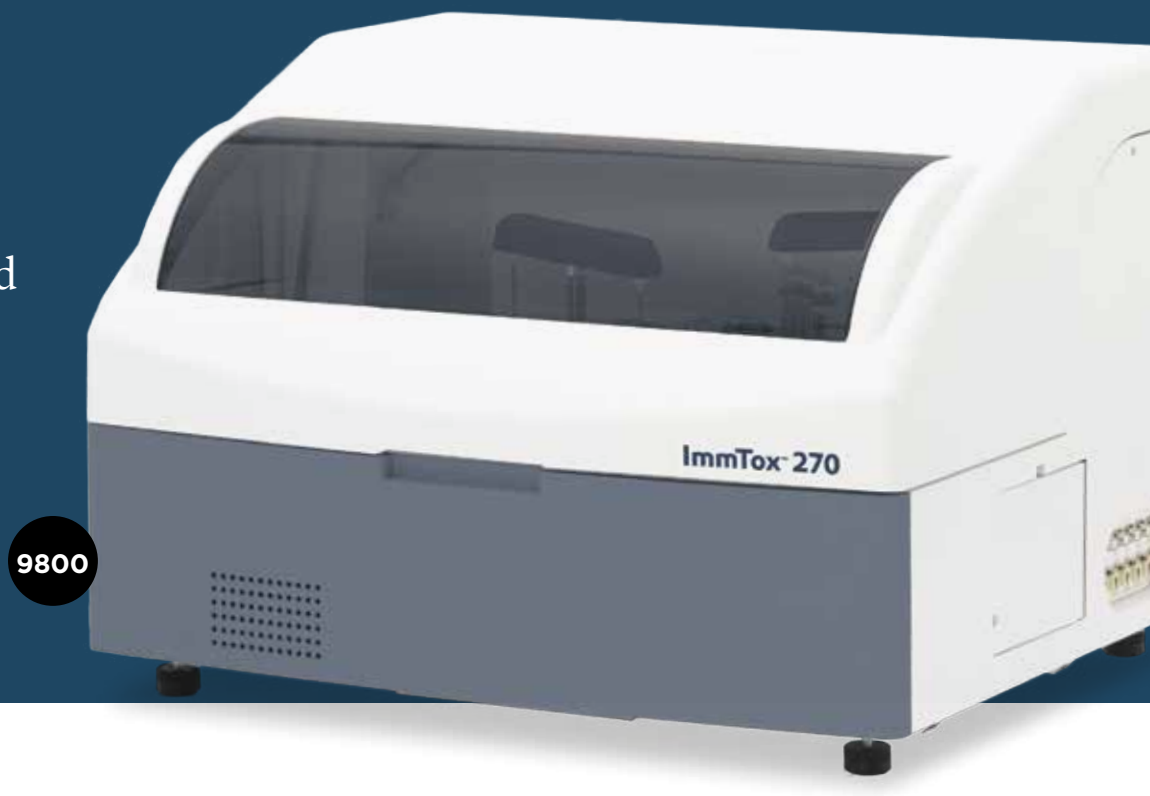
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ADAPTING TO CHANGE:

HOW RESILIENT IS YOUR LABORATORY?

The 21st century challenge is to redesign healthcare systems to be safe, efficient, effective, timely, equitable and patient-centered.

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EVALUATING MEMORY LOSS IN PRIMARY CARE: A NEW APPROACH

When an individual begins to show signs of memory loss, a physician's greatest challenge is often discovering the underlying cause of symptoms.

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3 THINGS PATIENTS REALLY WANT FROM THEIR DOCTORS

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Adapting to Change:

HOW RESILIENT IS YOUR LABORATORY?

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP),
TECHNICAL WRITER /QUALITY ADVISOR, COLA RESOURCES, INC.

Introduction

The 21st century challenge is to redesign healthcare systems to be safe, efficient, effective, timely, equitable and patient-centered. Laboratory medicine is integral to many of these objectives, involving disease prevention, diagnosis, treatment, and management.

As a result, the laboratory profession continues to undergo rapid change. Not only is there an impact through advances in technology, with new tests and test methodologies, new modes of communication, and new capacities for storage, retrieval and analysis and dissemination of data, but through emerging socio-political trends resulting in changes to the very structure of organized medicine, and how medical care is delivered. These include major legislation such as the Affordable Care Act

which encourages shifts from private practice to integrated healthcare networks; and the development of new models of healthcare delivery such as Accountable Care Organizations, which mandate value-based compensation models. These changes, whether on a macro institutional level, or micro departmental level, impact our laboratories. Millions more insured will lead to significantly increased demand for laboratory services at the same time that baby boomer staff (who have been the backbone of laboratory staffing since the 1960's) are retiring in large numbers, but with fewer schools training replacements. Exacerbating this is the continuing growth of tests available (currently at least 3500 tests), new specialties, new global health issues (i.e. Opiod epidemic), accelerating the increase in workload.

Challenges and Changes Forecast for the Laboratory Profession

The two main forces directly affecting laboratory operations are rapid technological advances (e.g. total laboratory automation, molecular diagnostics techniques, digital technology; point-of-care and remote testing, etc.) and resultant increased economic pressures, with the need to align to increasingly limited budgets.

One major outcome of the introduction and growth of digital technology, in particular,is the huge increase in the generation and utilization of data, both for immediate patient care needs as well as population health management and trend analysis. This has resulted in the laboratory becoming "information central" within the greater healthcare environment, touching almost every point of healthcare delivery. Under these circumstances it is easy to recognize that laboratory medicine has a pivotal role, increasingly integral to many clinical decisions on disease prevention, diagnosis, treatment and management. The overall challenge for the laboratory profession is to adapt to these rapid changes, while maintaining quality service.

A summary of these challenges include:

- Increased scope of services offered, requiring changes in laboratory organization and communication, including workflow, scheduling, reporting policies, data transmission and storage; expanded relationships with other healthcare providers; integrated roles for information technologists; and increased direct interaction with the public.

- New roles and responsibilities of the laboratory due to changes in healthcare delivery through integrated net work organizations —Accountable Care Organizations (ACOs) and Patient Centered Medical Homes (PCMHs), integrating the laboratory as a part of team-based care.

- The need for updating policies and procedures to reflect this new paradigm of increased scopes of practice and involvement.

- New personnel requirements, recruitment and training to ensure a competent workforce to meet these challenges.

- Adjusting to the new age of patient empowerment: patient initiated testing; and test results reported and interpreted directly to patients.

- Keeping up with the changing political and regulatory climate

- Changing population demographics and the need for interventions for specific subsets of the population; use of big data influencing government resource allocation.

Dealing with all these changes can be stressful for laboratory professionals. The clinical laboratory industry is already embracing networking, consolidation, integration, outsourcing, and creating additional value by providing knowledge services related to in vitro diagnostics. Clinical laboratory services are also increasingly defined by their value provided for patient outcomes. Already, there is evidence that ongoing technological developments have considerably improved the productivity of clinical laboratories.

The next thirty years comprise a perfect storm scenario for laboratory medicine in terms of meeting professional staffing needs to meet these challenges:

- Millions more people will be insured and able to access the healthcare system far more comprehensively than ever before, including laboratory services

- Millions of baby boomers adding to the post-65 year old demographic, requiring more frequent and intensive healthcare, including laboratory services

- Significant numbers of boomer clinical laboratory professionals are part of this retirement tidal wave, contributing to the shortage of available staff

- The continued rapid development of advanced technology such as molecular genetics. requiring ever more sophisticated instruments and advanced training by staff

- Increased competition from other healthcare professions that are able to promise and deliver on better working conditions, higher compensation, and greater recognition.

- Lack of adequate funding for enough schools and graduation capacity to provide the needed numbers of laboratory professionals.

Resilient Leadership

As a result, these times call for leadership that is more adaptive and agile than ever before, i.e. resilient leadership. This is leadership that understands change, and can adapt through creating an organizational culture of resilience;

going beyond continuous quality improvement to embrace change on an institutional as well as departmental level, enabling their laboratory operation to not only survive but prosper and grow.

Resilient Laboratories

These are laboratories that are able to respond effectively, and adapt to all kinds of changes in operation, internal and external demands, and expectations, through effective planning and resource allocation, thus allowing the continuation of normal services without compromising quality. Gaps in the continuity of healthcare threaten a patient's well-being and introduce the potential for adverse events. Whether, or how, a system responds to fill such gaps in care continuity indicates its resilience. Adaptations include new clinician initiatives, adaptive instrumentation, flexible staffing patterns, continuous quality improvement practices, and institutional networking leading to improvements in performance and service. These approaches make up the resilience that is built into the system to help accommodate demands for care. Resilience provides the means for organizations to target resource investments by integrating safety and productivity concerns. Quality work processes are not static properties of an organization, embracing resilience reflects a dynamic effort to maintain quality.

A culture of resilience

A culture of resilience recognizes the value of the laboratory staff, the stresses that they may be experiencing, the training that is needed, and the need to be supportive and understanding. It goes beyond a culture of continuous quality improvement to include trust, teamwork, tolerance, and a global perspective that more change is inevitable. The properties necessary for resilient organizations include:

Top Management commitment: to recognize performance concerns and addresses them with continuous and extensive follow-through based on applying competency improvement processes utilizing coaching and management observation.

Key management strategies include: providing staff with key information about future plans for the development of the laboratory, and involving the staff when possible; and determining how to implement these changes through adjustments to job assignments; staffing levels; policies and procedures; management of timelines and budgets.

The characteristics of a resilient laboratory include support for:

An open and fair culture: the reporting of issues, problems, events, and errors throughout the organization is supported and encouraged, but culpable behaviors are not tolerated.

A Learning culture: Wherein issues, problems, events, and errors are handled with an eye toward cofrrection, and solution, not denial; but not a "blame game" attitude either

Realism: Management is aware of any potential for serious problems and events due to weaknesses inherent in their operation, and continuously monitor these.

Awareness: Management collects ongoing data to gather insight into quality of performance, problems, and the state of safety defenses. Utilizes the staff for feedback and innovative ideas.

Flexibility: New or complex problems are handled in a way that maximizes the ability to solve the problem without disrupting overall work.

Transparency: Management keeps staff informed of all happenings, both good and bad. This can open up new avenues of discussion, problem-solving, and team-building.

Resilience relies on constant feedback from the staff regarding the effectiveness of the changes made by management. Additional steps that enhance the ability of the laboratory to successfully adapt to these challenges include:

1. Encouraging two-way communication

2. Recognize and reward achievement.

3. Help employees succeed. Provide employees with the resources and support to do their work, and as they show signs of readiness, be willing to entrust them with new tasks and greater responsibility.

4. Provide continuing education. This should include a formal orientation program, cross-functional training, maintenance of professional skills, coaching, career development, and personal development.

Out of this develops a resilient innovative workforce, one that is capable of adaptively learning to correct errors and to take advantage of new opportunities (e.g., digital technology; remote testing; ACOs), to improve quality of service.

The end result is the leveling of silos, enhancing communication, creating a workforce that is not hesitant to innovate and adapt to change; feels appreciated and experiences less stress when change is needed.

Irwin Z. Rothenberg is a Technical Writer/Quality Advisor for COLA's Educational subsidiary, COLA Resources, Inc. (CRI), a leader in online continuing education for physicians, laboratory personnel, and allied health professionals. CRI offers continuing education through online courses, informational products in both electronic and hard copy form, webinars on cutting-edge technology and regulatory issues, and CRI on-site Symposia for Clinical Laboratories, providing live educational sessions and interactive workshops with leading industry organizations. For more information, visit their website at www.criedu.org or call 1-800-981-9883.



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[1]Johansson MA et al. (2021) SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. JAMA Netw. Open 4, e2035057–e2035057

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INDICATIONS AND USAGE

PEMAZYRE is the first FDA-approved therapy for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

The major efficacy outcomes were evaluated in 107 patients with an FGFR2 fusion or non-fusion rearrangement* in a multicenter, open-label, single-arm study of 146 total patients with locally advanced unresectable or metastatic cholangiocarcinoma who had received ≥1 previous line of systemic therapy.[1,†]

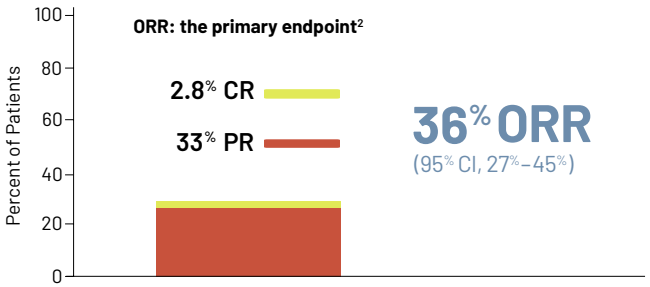
Patients receiving PEMAZYRE achieved durable responses

Median DoR was **9.1** months[1,‡]

Patients with DoR:

- **≥6 months: 63% (n=24)**
- **≥12 months: 18% (n=7)**

Clinical response rates of PEMAZYRE[1]



Efficacy evaluable population (N=107)

Note: Data are from IRC per RECIST v1.1, and CR and PR are confirmed.

*Determined by a clinical trial assay performed at a central laboratory.

†Patients received PEMAZYRE in 21-day cycles at a dosage of 13.5 mg orally once daily for 14 consecutive days, followed by 7 days off therapy, until disease progression or unacceptable toxicity occurred. The major efficacy outcome measures were ORR and DoR, as determined by IRC according to RECIST v1.1.

‡95% CI, 6.0-14.5 months and was calculated using the Brookmeyer and Crowley's method.[1]

CI, confidence interval; DoR, duration of response; IRC, independent review committee; ORR, overall response rate; RECIST, Response Evaluation Criteria in Solid Tumors.

Molecular profiling is necessary to detect FGFR2 fusions or rearrangements

A next-generation sequencing assay, such as FoundationOne® CDx, meets the following criteria to detect FGFR2 fusions[3-6]:

- Specifically detects FGFR2 fusions (distinct from FGFR2 mutations)
- Detects FGFR2 fusions with a wide range of fusion partners (whether known or unknown)

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IMPORTANT SAFETY INFORMATION

Ocular Toxicity

Retinal Pigment Epithelial Detachment (RPED): PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia. Clinical trials of PEMAZYRE did not conduct routine monitoring including optical coherence tomography (OCT) to detect asymptomatic RPED; therefore, the incidence of asymptomatic RPED with PEMAZYRE is unknown.

Among 466 patients who received PEMAZYRE across clinical trials, RPED occurred in 6% of patients, including Grade 3-4 RPED in 0.6%. The median time to first onset of RPED was 62 days. RPED led to dose interruption of PEMAZYRE in 1.7% of patients, and dose reduction and permanent discontinuation in 0.4% and in 0.4% of patients, respectively. RPED resolved

continued

Please see Important Safety Information for PEMAZYRE continued on the adjacent page.

IMPORTANT SAFETY INFORMATION (CONTINUED)

or improved to Grade 1 levels in 87.5% of patients who required dosage modification of PEMAZYRE for RPED.

Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended in the prescribing information for PEMAZYRE.

Dry Eye: Among 466 patients who received PEMAZYRE across clinical trials, dry eye occurred in 27% of patients, including Grade 3-4 in 0.6% of patients. Treat patients with ocular demulcents as needed.

Hyperphosphatemia and Soft Tissue Mineralization

PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE. Among 466 patients who received PEMAZYRE across clinical trials, hyperphosphatemia was reported in 92% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-169). Phosphate lowering therapy was required in 29% of patients receiving PEMAZYRE.

Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is >5.5 mg/dL. For serum phosphate levels >7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia as recommended in the prescribing information.

Embryo-Fetal Toxicity

Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg.

Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose.

Adverse Reactions

Serious adverse reactions occurred in 45% of patients receiving PEMAZYRE. Serious adverse reactions in ≥2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, bile duct obstruction, cholangitis, sepsis, and pleural effusion.

Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥1% of patients included intestinal obstruction and acute kidney injury.

Dosage interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, asthenia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, onychomadesis, and hypotension.

Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, asthenia, and onychomadesis.

Clinically relevant adverse reactions occurring in ≤10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 1.3% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N=466]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

The most common adverse reactions (incidence ≥20%) were hyperphosphatemia (60%), alopecia (49%), diarrhea (47%), nail toxicity (43%), fatigue (42%), dysgeusia (40%), nausea (40%), constipation (35%), stomatitis (35%), dry eye (35%), dry mouth (34%), decreased appetite (33%), vomiting (27%), arthralgia (25%), abdominal pain (23%), hypophosphatemia (23%), back pain (20%), and dry skin (20%).

Drug Interactions

Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce the dose of PEMAZYRE if concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE.

Special Populations

Advise lactating women not to breastfeed during treatment with PEMAZYRE and for 1 week after the final dose.

Reduce the recommended dose of PEMAZYRE for patients with severe renal impairment as described in the prescribing information.

Reduce the recommended dose of PEMAZYRE for patients with severe hepatic impairment as described in the prescribing information.

Please see the Brief Summary of Prescribing Information on the following pages.

References: 1. PEMAZYRE (pemigatinib) Prescribing Information. Incyte Corporation. **2.** Abou-Alfa GK, Sahai V, Hollebecque A, et al. *Lancet Oncol.* 2020;21(5):671-684. **3.** Lowery MA, Ptashkin R, Jordan E, et al. *Clin Cancer Res.* 2018;24(17):4154-4161. **4.** Javle MM, Murugesan K, Shroff RT, et al. *J Clin Oncol.* 2019;37(15 suppl):4087. **5.** Hollebecque A, de Bono JS, Plummer R, et al. *Ann Oncol.* 2019;30(suppl 1):mdz029. **6.** Frampton GM, Fichtenholtz A, Otto GA, et al. *Nat Biotechnol.* 2013;31(11):1023-1031.

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BRIEF SUMMARY: For Full Prescribing Information, see package insert.
INDICATIONS AND USAGE PEMAZYRE is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test *[see Dosage and Administration (2.1) in Full Prescribing Information]*. This indication is approved under accelerated approval based on overall response rate and duration of response *[see Clinical Studies (14.1) in Full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
CONTRAINDICATIONS None.
WARNINGS AND PRECAUTIONS Ocular Toxicity Retinal Pigment Epithelial Detachment (RPED) PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia. Clinical trials of PEMAZYRE did not conduct routine monitoring including optical coherence tomography (OCT) to detect asymptomatic RPED; therefore, the incidence of asymptomatic RPED with PEMAZYRE is unknown. Among 466 patients who received PEMAZYRE across clinical trials, RPED occurred in 6% of patients, including Grade 3-4 RPED in 0.6%. The median time to first onset of RPED was 62 days. RPED led to dose interruption of PEMAZYRE in 1.7% of patients, and dose reduction and permanent discontinuation in 0.4% and in 0.4% of patients, respectively. RPED resolved or improved to Grade 1 levels in 87.5% of patients who required dosage modification of PEMAZYRE for RPED. Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended *[see Dosage and Administration (2.3) in Full Prescribing Information]*. Dry Eye Among 466 patients who received PEMAZYRE across clinical trials, dry eye occurred in 27% of patients, including Grade 3-4 in 0.6% of patients. Treat patients with ocular demulcents as needed.
Hyperphosphatemia and Soft Tissue Mineralization PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE *[see Clinical Pharmacology (12.2) in Full Prescribing Information]*. Among 466 patients who received PEMAZYRE across clinical trials, hyperphosphatemia was reported in 92% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-169). Phosphate lowering therapy was required in 29% of patients receiving PEMAZYRE. Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is > 5.5 mg/dL. For serum phosphate levels > 7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia *[see Dosage and Administration (2.3) in Full Prescribing Information]*. **Embryo-Fetal Toxicity** Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose *[see Use in Specific Populations (8.1, 8.3) in Full Prescribing Information]*. **ADVERSE REACTIONS** The following adverse reactions are discussed elsewhere in the labeling: • Ocular Toxicity *[see Warnings and Precautions (5.1) in Full Prescribing Information]* • Hyperphosphatemia and Soft Tissue Mineralization *[see Warnings and Precautions (5.2) in Full Prescribing Information]*. **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 PEMAZYRE was evaluated in FIGHT-202, which included 146 patients with previously treated, locally advanced or metastatic cholangiocarcinoma *[see Clinical Studies (14.1) in Full Prescribing Information]*. Patients were treated orally with PEMAZYRE 13.5 mg once daily for 14 days on followed by 7 days off therapy until disease progression or unacceptable toxicity. The median duration of treatment was 181 days (range: 7 to 730 days). The median age of PEMAZYRE-treated patients was 59 years (range 26-78), 58% were females, and 71% were White. Serious adverse reactions occurred in 45% of patients receiving PEMAZYRE. Serious adverse reactions in ≥ 2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, bile duct obstruction, cholangitis, sepsis, and pleural effusion. Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥ 1% of patients included intestinal obstruction and acute kidney injury. Dosage interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥ 1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, asthenia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, onychomadesis, and hypotension. Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥ 1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, asthenia, and onychomadesis. Table 1 summarizes the adverse reactions in FIGHT-202. Table 2 summarizes laboratory abnormalities in FIGHT-202.

Table 1: Adverse Reactions (≥ 15%) in Patients Receiving PEMAZYRE in FIGHT-202

	PEMAZYRE N=146	
Adverse Reaction	**All Grades[a] (%)**	**Grades ≥ 3* (%)**
Metabolism and nutrition disorders		
Hyperphosphatemia[b]	60	0
Decreased appetite	33	1.4
Hypophosphatemia[c]	23	12
Dehydration	15	3.4
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Nail toxicity[d]	43	2.1
Dry skin	20	0.7
Palmar-plantar erythrodysesthesia syndrome	15	4.1
Gastrointestinal disorders		
Diarrhea	47	2.7
Nausea	40	2.1
Constipation	35	0.7
Stomatitis	35	5
Dry mouth	34	0
Vomiting	27	1.4
Abdominal pain	23	4.8
General disorders		
Fatigue	42	4.8
Edema peripheral	18	0.7
Nervous system disorders		
Dysgeusia	40	0
Headache	16	0
Eye disorders		
Dry eye[e]	35	0.7
Musculoskeletal and connective tissue disorders		
Arthralgia	25	6
Back pain	20	2.7
Pain in extremity	19	2.1

Table 1 continued above.

Table 1 continued.

	PEMAZYRE N=146	
Adverse Reaction	**All Grades[a] (%)**	**Grades ≥ 3* (%)**
Infections and infestations		
Urinary tract infection	16	2.7
Investigations		
Weight loss	16	2.1

*Only Grades 3 – 4 were identified.
[a] Graded per NCI CTCAE 4.03.
[b] Includes hyperphosphatemia and blood phosphorous increased; graded based on clinical severity and medical interventions taken according to the "investigations-other, specify" category in NCI CTCAE v4.03.
[c] Includes hypophosphatemia and blood phosphorous decreased.
[d] Includes nail toxicity, nail disorder, nail discoloration, nail dystrophy, nail hypertrophy, nail ridging, nail infection, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis, and paronychia.
[e] Includes dry eye, keratitis, lacrimation increased, pinguecula, and punctate keratitis.

Clinically relevant adverse reactions occurring in ≤ 10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 1.3% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N=466]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Table 2: Select Laboratory Abnormalities (≥ 10%) Worsening from Baseline in Patients Receiving PEMAZYRE in FIGHT-202

	PEMAZYRE[a] N=146	
Laboratory Abnormality	**All Grades[b] (%)**	**Grades ≥ 3 (%)**
Hematology		
Decreased hemoglobin	43	6
Decreased lymphocytes	36	8
Decreased platelets	28	3.4
Increased leukocytes	27	0.7
Decreased leukocytes	18	1.4
Chemistry		
Increased phosphate[c]	94	0
Decreased phosphate	68	38
Increased alanine aminotransferase	43	4.1
Increased aspartate aminotransferase	43	6
Increased calcium	43	4.1
Increased alkaline phosphatase	41	11
Increased creatinine[d]	41	1.4
Decreased sodium	39	12
Increased glucose	36	0.7
Decreased albumin	34	0
Increased urate	30	10
Increased bilirubin	26	6
Decreased potassium	26	5
Decreased calcium	17	2.7
Increased potassium	12	2.1
Decreased glucose	11	1.4

[a]The denominator used to calculate the rate varied from 142-146 based on the number of patients with a baseline value and at least one post-treatment value.
[b]Graded per NCI CTCAE 4.03.
[c]Based on CTCAE 5.0 grading.
[d]Graded based on comparison to upper limit of normal.

Increased Creatinine Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **DRUG INTERACTIONS Effect of Other Drugs on PEMAZYRE** Strong and Moderate CYP3A Inducers Concomitant use of PEMAZYRE with a strong or moderate CYP3A inducer decreases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may reduce the efficacy of PEMAZYRE. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE. Strong and Moderate CYP3A Inhibitors Concomitant use of a strong or moderate CYP3A inhibitor with PEMAZYRE increases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may increase the incidence and severity of adverse reactions. Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce PEMAZYRE dosage if concomitant use of strong and moderate CYP3A inhibitors cannot be avoided *[see Dosage and Administration (2.4) in Full Prescribing Information]*. **USE IN SPECIFIC POPULATIONS Pregnancy** Risk Summary Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm or loss of pregnancy when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in Full Prescribing Information]*. There are no available data on the use of PEMAZYRE in pregnant women. Oral administration of pemigatinib to pregnant rats during the period of organogenesis at maternal plasma exposures below the human exposure at the clinical dose of 13.5 mg resulted in fetal malformations, fetal growth retardation, and embryo-fetal death (*see Data*). 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* Once daily oral administration of pemigatinib to pregnant rats during the period of organogenesis resulted in 100% embryofetal mortality due to post-implantation loss at doses ≥ 0.3 mg/kg (approximately 0.6 times the human exposure based on AUC at the clinical dose of 13.5 mg). Fetal survival was unaffected at 0.1 mg/kg per day; however, once daily oral administration of pemigatinib at the 0.1 mg/kg dose level (approximately 0.2 times the human exposure based on AUC at the clinical dose of 13.5 mg) resulted in reduced mean fetal body weight and an increase in fetal skeletal and visceral malformations, major blood vessel variations, and reduced ossification. **Lactation** Risk Summary There are no data on the presence of pemigatinib or its metabolites in human milk or their effects on either the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children from PEMAZYRE, advise women not to breastfeed during treatment and for 1 week after the final dose. **Females and Males of Reproductive Potential** Pregnancy Testing Verify pregnancy status of females of reproductive potential prior to initiating PEMAZYRE *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. Contraception PEMAZYRE can cause fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. **Females** Advise females of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Males** Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Pediatric Use** The safety and effectiveness of PEMAZYRE have not been established in pediatric patients. Animal Toxicity Data In 4- or 13-week repeat-dose toxicology studies in rats and non-human primates, animals displayed toxicities in bone and teeth at pemigatinib exposures lower than the human exposure at the clinical dose of 13.5 mg. Physeal and cartilage dysplasia were present in multiple bones in both species, and tooth (incisor) abnormalities (complete loss of ameloblasts with associated secondary changes) occurred in rats. Six weeks after cessation of dosing, these findings did not show complete evidence of recovery, and additional tooth-related findings (mal-aligned, whitened, broken, and trimmed/thinned incisors) developed in the 13-week study. **Geriatric Use** In FIGHT-202, 32% of patients were 65 years and older, and 8% of patients were 75 years and older. No overall differences in safety or effectiveness were observed between these patients and younger patients. **Renal Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m^2, estimated by Modification of Diet in Renal Disease [MDRD] equation) *[see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild or moderate renal impairment (eGFR 30 to 89 mL/min/1.73 m^2). No dosage adjustment is recommended for patients with end-stage renal disease (eGFR < 15 mL/min/1.73 m^2) who are receiving intermittent hemodialysis. *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **Hepatic Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe hepatic impairment (total bilirubin > 3 × ULN with any AST) *[see Dosage and Administration (2.6) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild (total bilirubin > upper limit of normal [ULN] to 1.5 × ULN or AST > ULN) or moderate (total bilirubin >1.5–3 × ULN with any AST) hepatic impairment *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*.

PEMAZYRE is a registered trademark of Incyte Corporation.
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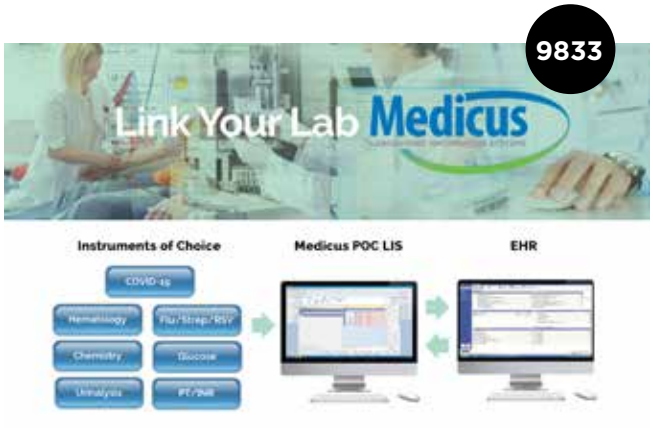
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POWER REIMAGINED

144-Week and 96-Week Data for Treatment-Naïve and Virologically Suppressed Adults Living With HIV-1



INDICATION

DOVATO is indicated as a complete regimen to treat HIV-1 infection in adults with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of DOVATO.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1: EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

Warnings and precautions

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

Please see additional Important Safety Information for DOVATO on the following pages.

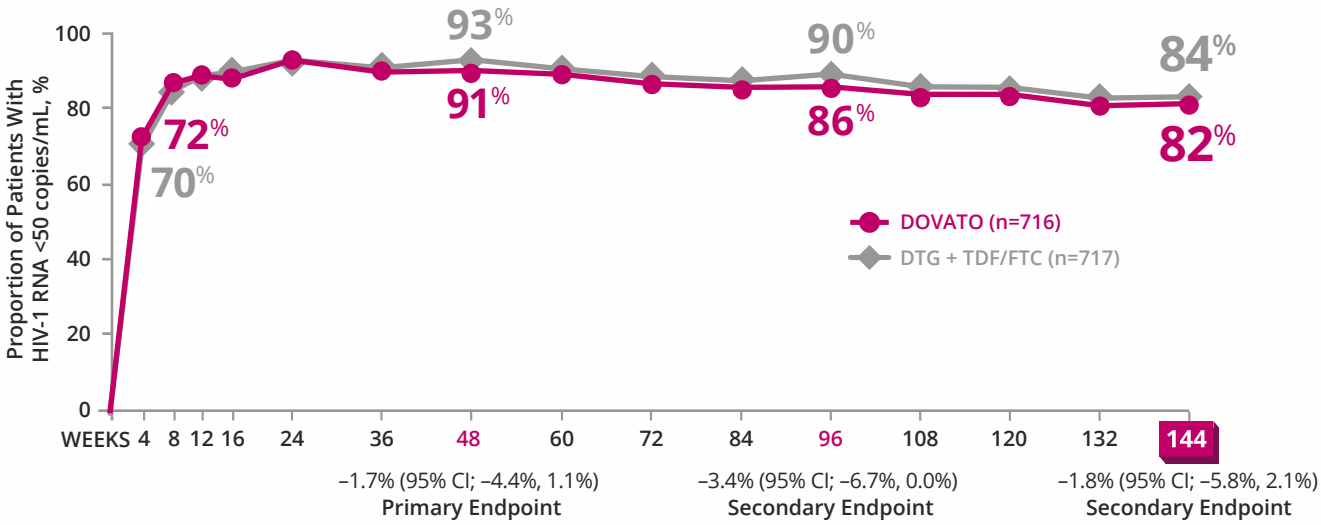
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Not an actual patient.

Proven, Durable Efficacy
Through 144 Weeks in Treatment-Naïve Adults

GEMINI 1 & 2—DOVATO Was Noninferior to DTG + TDF/FTC at 144 Weeks

Pooled Virologic Response (ITT–E; Snapshot analysis)[1-3]



The evaluation of antiviral activity over time was a prespecified secondary endpoint, ITT–E population.

DOVATO Virologic Suppression | **RAPID** at Week 4 | **POWERFUL** at Week 48 | **SUSTAINED** at Week 144

GEMINI 1 & 2: Treatment-Naïve Trial Design

Identically designed, Phase 3, randomized, double-blind to Week 96, (open-label from Week 96 to Week 144), noninferiority trials in treatment-naïve adult patients with HIV-1 (≥18 years old). Patients included in the trial had to have CrCL ≥50 mL/min and no severe hepatic impairment (Child-Pugh Class C). Patients with HBV or major resistance-associated mutations were excluded from the clinical trials. At baseline across both treatment arms, 9% were CDC Stage 3 (AIDS), 20% had HIV-1 RNA >100,000 copies/mL, and 9% had $CD4^+$ T-cell count ≤200 cells/mm^3. Primary endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL at Week 48 using FDA snapshot analysis (ITT–E) with 10% noninferiority margin.[2]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Embryo Fetal Toxicity:

- Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
- Pregnancy testing is recommended before initiation of DOVATO. Individuals of childbearing potential should be counseled on the consistent use of effective contraception

Lactic Acidosis and Severe Hepatomegaly With Steatosis:

Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug interactions).

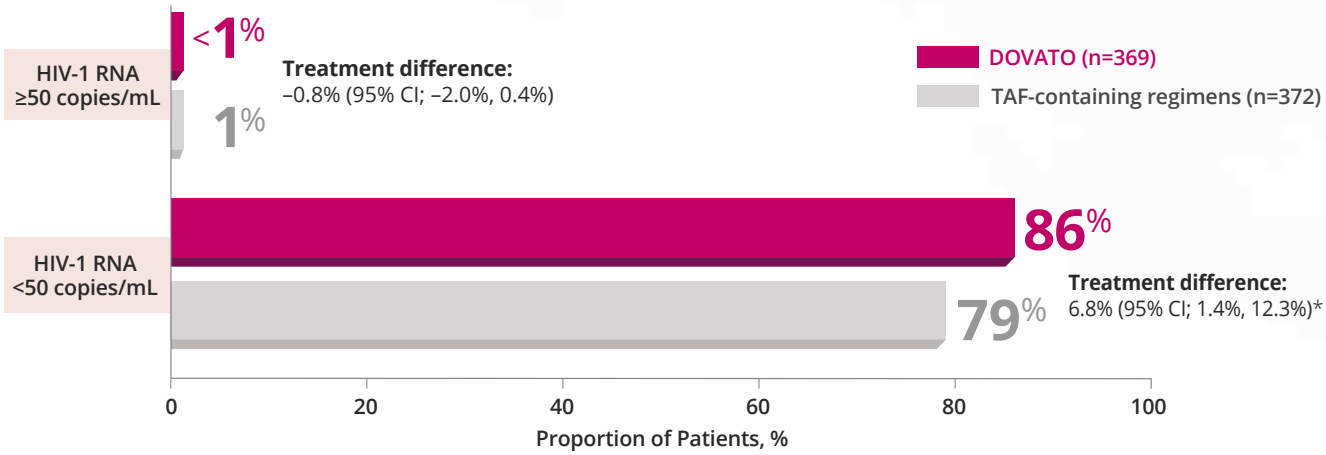
Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.

Please see additional Important Safety Information for DOVATO throughout.
Please see Brief Summary of Prescribing Information for DOVATO, including Boxed Warning, on the following pages.

Proven, Durable Efficacy
Through 96 Weeks in Virologically Suppressed Adults

DOVATO Was Shown to Be as Effective as TAF-Containing Regimens at 96 Weeks

Prespecified Secondary Endpoint—Virologic Response (ITT–E; Snapshot analysis)[4]



*The number of patients with no virologic data at Week 96 due to COVID-19 was a primary driver in the treatment difference in the secondary endpoint.

TANGO: Virologically Suppressed Trial Design

An ongoing, Phase 3, noninferiority trial in participants who were on a stable, suppressive (HIV-1 RNA <50 copies/mL) TAF-containing regimen for >6 months.[†] Participants had no history of virologic failure, no documented NRTI or INSTI resistance, no severe hepatic impairment (Child-Pugh class C), and were HBV negative. At baseline across both treatment arms, 5% were CDC Stage 3 (AIDS) and 98% had CD4+ T-cell count ≥200 cells/mm^3. Primary endpoint was the proportion of patients with HIV-1 RNA ≥50 copies/mL at Week 48 using FDA Snapshot analysis (ITT–E) with 4% noninferiority margin, –8% noninferiority margin for secondary endpoint.[5]

[†]TAF/FTC + EVG/c, DTG, RAL, RPV, NVP, EFV, bATV, or bDRV.[6]

bATV=boosted atazanavir; bDRV=boosted darunavir; CDC=Centers for Disease Control and Prevention; CI=confidence interval; CrCl=creatinine clearance; DTG=dolutegravir; EFV=efavirenz; EVG/c=elvitegravir/cobicistat; FTC=emtricitabine; HBV=hepatitis B virus; INSTI=integrase strand transfer inhibitor; ITT–E=intent-to-treat–exposed; NRTI=nucleoside reverse transcriptase inhibitor; NVP=nevirapine; RAL=raltegravir; RPV=rilpivirine; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

The most common adverse reactions (incidence ≥2%, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

Drug interactions

- Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
- DOVATO is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
- Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established. Advise individuals of childbearing potential of the potential risk of neural tube defects. Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

A High Barrier to Resistance in Treatment-Naïve and Virologically Suppressed Adults

GEMINI 1 & 2: Treatment-Naïve Adults[1]

- 12 participants in the DOVATO arm and 9 participants in the DTG + TDF/FTC arm had CVW* at 144 weeks
- Among all trial participants: In the DOVATO arm, 1 participant with reported non-adherence on the separate pills of DTG + 3TC developed resistance-associated mutations.† In the DTG + TDF/FTC arm, there were no resistance mutations observed among participants

TANGO: Virologically Suppressed Adults[4]

- 0 participants in the DOVATO arm and 3 participants in the TAF-containing regimens arm had CVW* at 96 weeks
- There were 0 cases of treatment-emergent resistance among participants across both treatment arms

*In GEMINI 1 & 2, CVW was defined as either virologic nonresponse (a decrease in plasma HIV-1 RNA of <1 $\log_{10}$ copies/mL by Week 12, with subsequent confirmation, unless plasma HIV-1 RNA is <200 copies/mL or confirmed plasma HIV-1 RNA ≥200 copies/mL on or after Week 24) or virologic rebound (confirmed rebound in plasma HIV-1 RNA levels to ≥200 copies/mL after prior confirmed suppression to <200 copies/mL). In TANGO, patients met confirmed virological withdrawal criteria if they had 1 assessment with HIV-1 RNA ≥200 copies/mL after Day 1 with an immediately prior HIV-1 RNA ≥50 copies/mL.[2,5] Because no participants in the DOVATO arm met CVW criteria, none were evaluated for treatment-emergent resistance.

†Resistance-associated mutation: M184V at Week 132 (NRTI); R263R/K (INSTI) at Week 144. The subject was withdrawn from the study and re-suppressed on a DTG-containing regimen.[1]

DRUG-RELATED AEs AND DISCONTINUATION RATES

Treatment-Naïve Patients Through 144 Weeks[6]

- Treatment-emergent ADRs (incidence ≥2%; all grades) in patients receiving DOVATO and DTG + TDF/FTC, respectively: headache (3% vs 4%), nausea (2% vs 6%), diarrhea (2% vs 3%), insomnia (2% vs 3%), fatigue‡ (2% vs 2%), dizziness (1% vs 2%), and anxiety (2% vs <1%)

‡Includes fatigue, asthenia, and malaise.

Virologically Suppressed Patients Through 96 Weeks[4]

- 6% of participants taking DOVATO reported any drug-related AEs Grades 2 to 5 compared with 2% in the TAF-containing regimens arm
- Treatment-emergent ADRs (Grades 2 to 5) with ≥0.5% frequency in patients receiving DOVATO and a TAF-containing regimen, respectively: depression (<1% vs <1%), insomnia (1% vs 0%), constipation (<1% vs <1%), weight increased (<1% vs <1%), and flatulence (<1% vs 0%)

3TC=lamivudine; ADR=adverse drug reaction; AE=adverse event; CVW=confirmed virologic withdrawal.

IMPORTANT SAFETY INFORMATION (cont'd)
Use in specific populations (cont'd)

- **Females and Males of Reproductive Potential:** Pregnancy testing is recommended before initiation of DOVATO. Counsel individuals of childbearing potential taking DOVATO on the consistent use of effective contraception
- **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

Please see additional Important Safety Information for DOVATO on the previous pages.
Please see Brief Summary of Prescribing Information for DOVATO, including Boxed Warning, on the following pages.

References: 1. Cahn P, Madero JS, Arribas JR, et al. Durable efficacy of dolutegravir (DTG) plus lamivudine (3TC) in antiretroviral treatment-naïve adults with HIV-1 infection—3-year results from the GEMINI studies. Presented at: HIV Glasgow 2020; October 5-8, 2020; Virtual. Poster P018. **2.** Cahn P, Madero JS, Arribas JR, et al; and GEMINI Study Team. Dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate and emtricitabine in antiretroviral-naive adults with HIV-1 infection (GEMINI-1 and GEMINI-2): week 48 results from two multicentre, double-blind, randomised, non-inferiority, phase 3 trials. *Lancet*. 2019;393(10167):143-155. **3.** Cahn P, Madero JS, Arribas JR, et al. Durable efficacy of dolutegravir plus lamivudine in antiretroviral treatment–naive adults with HIV-1 infection: 96-week results from the GEMINI-1 and GEMINI-2 randomized clinical trials. *J Acquir Immune Defic Syndr*. 2020;83(3):310-318. **4.** van Wyk J, Ajana F, Bisshop F, et al. Switching to DTG/3TC fixed-dose combination (FDC) is non-inferior to continuing a TAF-based regimen (TBR) in maintaining virologic suppression through 96 weeks (TANGO study). Presented at: HIV Glasgow 2020; October 5-8, 2020; Virtual. Slides O441. **5.** van Wyk J, Ajana F, Bisshop F, et al. Efficacy and safety of switching to dolutegravir/lamivudine fixed-dose 2-drug regimen vs continuing a tenofovir alafenamide–based 3- or 4-drug regimen for maintenance of virologic suppression in adults living with human immunodeficiency virus type 1: phase 3, randomized, noninferiority TANGO Study. *Clin Infect Dis*. 2020;71(8):1920-1929. doi:10.1093/cid/ciz1243 **6.** Data on file, ViiV Healthcare.

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

DOLUTEGRAVIR DTG AT THE CORE

BRIEF SUMMARY

DOVATO (dolutegravir and lamivudine) tablets, for oral use

The following is a brief summary only; see full prescribing information, including boxed warning, for complete product information.

WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV-1): EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

CONTRAINDICATIONS

DOVATO is contraindicated in patients: with prior hypersensitivity reaction to dolutegravir or lamivudine; receiving dofetilide due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events.

WARNINGS AND PRECAUTIONS

Patients Co-infected with HIV-1 and HBV: Emergence of Lamivudine-Resistant HBV and the Risk of Posttreatment Exacerbations of HBV: All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of Lamivudine-Resistant HBV: Safety and efficacy of lamivudine have not been established for treatment of chronic HBV in subjects dually infected with HIV-1 and HBV. Emergence of HBV variants associated with resistance to lamivudine has been reported in HIV-1–infected subjects who have received lamivudine-containing antiretroviral regimens in the presence of concurrent infection with HBV. If a decision is made to administer DOVATO to patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen. Severe Acute Exacerbations of HBV in Patients Co-infected with HIV-1 and HBV: Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued products containing lamivudine, and may occur with discontinuation of DOVATO. Patients who are co-infected with HIV-1 and HBV who discontinue DOVATO should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment with DOVATO. If appropriate, initiation of anti-HBV therapy may be warranted, especially in patients with advanced liver disease or cirrhosis, since posttreatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure. **Hypersensitivity Reactions:** Hypersensitivity reactions have been reported with the use of dolutegravir, a component of DOVATO, and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury. These events were reported in <1% of subjects receiving dolutegravir in Phase 3 clinical trials. Discontinue DOVATO immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters or peeling of the skin, oral blisters or lesions, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing). Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated. Delay in stopping treatment with DOVATO or other suspect agents after the onset of hypersensitivity may result in a life-threatening reaction. **Hepatotoxicity:** Hepatic adverse events have been reported in patients receiving a dolutegravir-containing regimen. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or HBV reactivation particularly in the setting where anti-hepatitis therapy was withdrawn. Cases of hepatic toxicity, including elevated serum liver biochemistries, hepatitis, and acute liver failure, have also been reported in patients receiving a dolutegravir-containing regimen who had no pre-existing hepatic disease or other identifiable risk factors. Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ (abacavir, dolutegravir, and lamivudine). Monitoring for hepatotoxicity is recommended. **Embryo-Fetal Toxicity:** An ongoing observational study showed an association between dolutegravir and an increased risk of neural tube defects when dolutegravir was administered at the time of conception and in early pregnancy. As there is limited understanding of the association of reported types of neural tube defects with dolutegravir use, inform individuals of childbearing potential, including those actively trying to become pregnant, about the potential increased risk of neural tube defects with DOVATO. Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester. Pregnancy testing is recommended before initiation of DOVATO in individuals of childbearing potential. Individuals of childbearing potential should be counseled on the consistent use of effective contraception. DOVATO may be considered during the second and third trimesters of pregnancy if the expected benefit justifies the potential risk to the pregnant woman and the fetus. **Lactic Acidosis and Severe Hepatomegaly with Steatosis:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including lamivudine (a component of DOVATO). A majority of these cases have been in women. Female sex and obesity may be risk factors for the development of lactic acidosis and severe hepatomegaly with steatosis in patients treated with antiretroviral nucleoside analogues. Monitor closely when administering DOVATO to any patient with known risk factors for liver disease. Treatment with DOVATO should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity, which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations. **Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:** The coadministration of DOVATO and other drugs may result in known or potentially significant drug interactions, some of which may lead to: Loss of therapeutic effect of DOVATO and possible development of resistance; Possible clinically significant adverse reactions from greater exposures of coadministered drugs. See Drug Interactions for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during therapy with DOVATO, review coadministered drugs during therapy with DOVATO, and monitor for the adverse reactions associated with the coadministered drugs. **Immune Reconstitution Syndrome:** Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including DOVATO. During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment. Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment.

ADVERSE REACTIONS

Clinical Trials Experience: Clinical Trials in Adults with No Antiretroviral Treatment History: The safety assessment of DOVATO in HIV-1–infected adults with no antiretroviral treatment history and with a plasma viral load ≤500,000 HIV-1 RNA copies/mL at the screening visit, is based on the pooled primary Week 96 analyses of data from 2 identical, multicenter, double-blind, controlled trials, GEMINI-1 and GEMINI-2. A total of 1,433 HIV-1–infected adults with no antiretroviral treatment history received either dolutegravir (TIVICAY) 50 mg plus lamivudine (EPIVIR) 300 mg, as a complete regimen once daily, or TIVICAY 50 mg plus fixed-dose combination tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) (TRUVADA), administered once daily. The rates of adverse events leading to discontinuation in the pooled analysis were 3% of subjects in both treatment arms. The most common adverse events leading to discontinuation were psychiatric disorders: 1% of subjects in both treatment arms. Adverse reactions (all grades) observed in at least 2% of subjects in either treatment arm of the Week 96 pooled analysis from GEMINI-1 and GEMINI-2 trials are provided in Table 2. The adverse reactions observed for TIVICAY plus EPIVIR in the Week 96 analysis of the pooled data from GEMINI-1 and GEMINI-2 were generally consistent with the adverse reaction profiles and severities for the individual components when administered with other antiretroviral agents.

(cont'd on next page)

Table 2. Adverse Reactions (All Grades) Reported in ≥2% of Subjects in Any Treatment Group in Adults with No Antiretroviral Treatment History in GEMINI-1 and GEMINI-2 (Week 96 Pooled Analysis)

Adverse Reaction	TIVICAY plus EPIVIR (n = 716)	TIVICAY plus TRUVADA (n = 717)
Headache	3%	4%
Nausea	2%	5%
Diarrhea	2%	3%
Insomnia	2%	3%
Fatigue[a]	2%	2%
Anxiety	2%	1%
Dizziness	1%	2%

[a]Fatigue: includes fatigue, asthenia, and malaise.

Adverse reactions of at least Grade 2 occurring in ≥1% of subjects treated with TIVICAY plus EPIVIR were headache, anxiety, and suicidal ideation (all at 1%). *Less Common Adverse Reactions:* The following adverse reactions occurred in <2% of subjects receiving dolutegravir plus lamivudine or are from studies described in the prescribing information of the individual components, TIVICAY (dolutegravir) and EPIVIR (lamivudine). Some events have been included because of their seriousness and assessment of potential causal relationship. – *Blood and Lymphatic Systems Disorders:* Anemia, neutropenia, thrombocytopenia. – *Gastrointestinal Disorders:* Abdominal discomfort, abdominal pain, flatulence, upper abdominal pain, vomiting. – *General:* Fever. – *Hepatobiliary Disorders:* Hepatitis. – *Immune System Disorders:* Hypersensitivity, immune reconstitution syndrome. – *Musculoskeletal Disorders:* Myositis. – *Nervous System Disorders:* Somnolence. – *Psychiatric Disorders:* Abnormal dreams, depression. Suicidal ideation, attempt, behavior, or completion; these events were observed primarily in subjects with a pre-existing history of depression or other psychiatric illness. – *Renal and Urinary Disorders:* Renal impairment. – *Skin and Subcutaneous Tissue Disorders:* Pruritus, rash.

Clinical Trials in Virologically Suppressed Adults: The safety of DOVATO in virologically suppressed adults was based on Week 48 data from 740 subjects in a randomized, parallel-group, open-label, multicenter, non-inferiority controlled trial (TANGO). Subjects who were on a stable suppressive tenofovir alafenamide-based regimen (TBR) were randomized to receive DOVATO once daily or continue with their TBR for up to 200 weeks. Overall, the safety profile of DOVATO in virologically suppressed adult subjects in the TANGO trial was similar to that of TIVICAY plus EPIVIR in subjects with no antiretroviral treatment history in the GEMINI trials.

Laboratory Abnormalities: Selected laboratory abnormalities with a worsening grade from baseline and representing the worst-grade toxicity are presented in Table 3. The mean change from baseline observed for selected lipid values is presented in Table 4.

Table 3. Selected Laboratory Abnormalities (Grades 2 to 4; Week 96 Pooled Analyses) in GEMINI-1 and GEMINI-2 Trials

Laboratory Parameter Abnormality	TIVICAY plus EPIVIR (n = 716)	TIVICAY plus TRUVADA (n = 717)
Alanine aminotransferase (ALT)		
Grade 2 (2.5 to <5.0 x ULN)	3%	4%
Grade 3 to 4 (≥5.0 x ULN)	3%	3%
Aspartate aminotransferase (AST)		
Grade 2 (2.5 to <5.0 x ULN)	4%	4%
Grade 3 to 4 (≥5.0 x ULN)	3%	3%
Total bilirubin		
Grade 2 (1.6 to <2.6 x ULN)	2%	3%
Grade 3 to 4 (≥2.6 x ULN)	1%	1%
Creatine kinase		
Grade 2 (6.0 to <10 x ULN)	4%	4%
Grade 3 to 4 (≥10.0 x ULN)	6%	7%
Hyperglycemia (glucose)		
Grade 2 (126 to 250 mg/dL)	9%	6%
Grade 3 to 4 (>250 mg/dL)	1%	1%
Hypophosphatemia (phosphate)		
Grade 2 (1.4 to <2.0 mg/dL)	9%	10%
Grade 3 to 4 (<1.4 mg/dL)	1%	1%
Lipase		
Grade 2 (1.5 to <3.0 x ULN)	6%	6%
Grade 3 to 4 (≥3.0 x ULN)	2%	4%

ULN = Upper limit of normal.

Table 4. Mean Change from Baseline in Fasted Lipid Values (Week 96 Pooled Analyses[a]) in GEMINI-1 and GEMINI-2 Trials

Laboratory Parameter Preferred Term	TIVICAY plus EPIVIR (n = 716)	TIVICAY plus TRUVADA (n = 717)
Cholesterol (mg/dL)	15	-6
HDL cholesterol (mg/dL)	7	3
LDL cholesterol (mg/dL)	6	-7
Triglycerides (mg/dL)	11	-11
Total cholesterol/HDL cholesterol ratio	-0.1	-0.4

[a]Subjects on lipid-lowering agents at baseline are excluded (TIVICAY plus EPIVIR, n = 30; TIVICAY plus TRUVADA, n = 23). The last available fasted, on-treatment lipid value prior to initiation of a lipid-lowering agent was carried forward in place of observed values after initiation of a lipid-lowering agent. A total of 40 and 16 subjects receiving TIVICAY plus EPIVIR and TIVICAY plus TRUVADA, respectively, initiated lipid-lowering agents post-baseline.

Changes in Serum Creatinine: Dolutegravir has been shown to increase serum creatinine due to inhibition of tubular secretion of creatinine without affecting renal glomerular function. Increases in serum creatinine occurred within the first 4 weeks of treatment in both arms and remained stable through 96 weeks. A mean change from baseline of 0.138 mg/dL and 0.176 mg/dL was observed after 96 weeks of treatment with TIVICAY plus EPIVIR and TIVICAY plus TRUVADA, respectively. These changes are not considered to be clinically relevant. **Postmarketing Experience:** The following adverse reactions have been identified during postmarketing experience in patients receiving a dolutegravir- or lamivudine-containing regimen. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Body as a Whole: Redistribution/accumulation of body fat. Endocrine and Metabolic: Hyperglycemia. General: Weakness. Hemic and Lymphatic: Anemia (including pure red cell aplasia and severe anemias progressing on therapy). Hepatic and Pancreatic: Lactic acidosis and hepatic steatosis, pancreatitis, posttreatment exacerbations of HBV. Hepatobiliary Disorders: Acute liver failure, hepatotoxicity. Hypersensitivity: Anaphylaxis, urticaria. Investigations: Weight increased. Musculoskeletal: Arthralgia, CPK elevation, muscle weakness, myalgia, rhabdomyolysis. Nervous System: Paresthesia, peripheral neuropathy. Skin: Alopecia.

DRUG INTERACTIONS

Coadministration with Other Antiretroviral Drugs: DOVATO is a complete regimen for the treatment of HIV-1 infection; therefore, coadministration with other antiretroviral drugs for the treatment of HIV-1 infection is not recommended. Information regarding potential drug-drug interactions with other antiretroviral drugs is not provided. **Potential for DOVATO to Affect Other Drugs:** Dolutegravir, a component of DOVATO, inhibits the renal organic cation transporters (OCT)2 and multidrug and toxin extrusion transporter (MATE)1; thus, it may increase plasma concentrations of drugs eliminated via OCT2 or MATE1 such as dofetilide, dalfampridine, and metformin. **Potential for Other Drugs to Affect the Components of DOVATO:** Dolutegravir is metabolized by uridine diphosphate (UDP)-glucuronosyl transferase (UGT)1A1 with some contribution from cytochrome P450 (CYP)3A. Dolutegravir is also a substrate of UGT1A3, UGT1A9, breast cancer resistance protein (BCRP), and P-glycoprotein (P-gp) in vitro. Drugs that induce those enzymes and transporters may decrease dolutegravir plasma concentrations and reduce the therapeutic effect of DOVATO. Coadministration of DOVATO and other drugs that inhibit these enzymes may increase dolutegravir plasma concentrations. Coadministration of dolutegravir with polyvalent cation-containing products may lead to decreased absorption of dolutegravir. **Established and Other Potentially Significant Drug Interactions:** No drug interaction studies were conducted with DOVATO. The drug interactions described are based on studies conducted with dolutegravir or lamivudine when administered alone. Information regarding potential drug interactions with DOVATO are provided below. These recommendations are based on either drug interaction trials or predicted interactions due to the expected magnitude of interaction and potential for serious adverse events or loss of efficacy. **Established and Other Potentially Significant Drug Interactions for DOVATO:** Alterations in dose may be recommended based on drug interaction trials or predicted interactions for the following drugs when coadministered with DOVATO:

(cont'd on next page)

BRIEF SUMMARY for DOVATO (dolutegravir and lamivudine) tablets (cont'd)

- **Antiarrhythmic:** dofetilide – coadministration is contraindicated with DOVATO.
- **Anticonvulsant:** carbamazepine – an additional dolutegravir 50-mg dose should be taken, separated by 12 hours from DOVATO.
- **Anticonvulsants:** oxcarbazepine, phenytoin, phenobarbital – avoid coadministration with DOVATO because there are insufficient data to make dosing recommendations.
- **Antidiabetic:** metformin – refer to the prescribing information for metformin for assessing the benefit and risk of concomitant use of DOVATO and metformin.
- **Antimycobacterial:** rifampin – an additional 50-mg dose of dolutegravir should be taken, separated by 12 hours from DOVATO.
- **Herbal product:** St. John's wort (*Hypericum perforatum*) – avoid coadministration with DOVATO because there are insufficient data to make dosing recommendations.
- **Medications containing polyvalent cations (e.g., Mg or Al):** cation-containing antacids or laxatives, sucralfate, buffered medications – administer DOVATO 2 hours before or 6 hours after taking medications containing polyvalent cations.
- **Oral calcium and iron supplements,** including multivitamins containing calcium or iron – when taken with food, DOVATO and supplements or multivitamins containing calcium or iron can be taken at the same time. Under fasting conditions, DOVATO should be taken 2 hours before or 6 hours after taking supplements containing calcium or iron.
- **Potassium channel blocker:** dalfampridine – elevated levels of dalfampridine increase the risk of seizures. The potential benefits of taking dalfampridine concurrently with DOVATO should be considered against the risk of seizures in these patients.
- **Sorbitol** – when possible, avoid use of sorbitol-containing medicines with DOVATO.

Consult the full Prescribing Information for potential drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to DOVATO during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263. Risk Summary: Data from an ongoing birth outcome surveillance study have identified an increased risk of neural tube defects when dolutegravir, a component of DOVATO, is administered at the time of conception. As defects related to closure of the neural tube occur from conception through the first 6 weeks of gestation, embryos exposed to dolutegravir from the time of conception through the first 6 weeks of gestation are at potential risk. Advise individuals of childbearing potential, including those actively trying to become pregnant, of the potential risk of neural tube defects with use of DOVATO. Assess the risks and benefits of DOVATO and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester. A benefit-risk assessment should consider factors such as feasibility of switching to another antiretroviral regimen, tolerability, ability to maintain viral suppression, and risk of HIV-1 transmission to the infant against the risk of neural tube defects associated with in utero dolutegravir exposure during critical periods of fetal development *(see Data)*. There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. **Lactation:** The Centers for Disease Control and Prevention recommends that HIV-1–infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Lamivudine, a component of DOVATO, is present in human milk. It is not known whether dolutegravir, a component of DOVATO, is present in human milk. When administered to lactating rats, dolutegravir was present in milk. There is no information on the effects of DOVATO or the components of DOVATO on the breastfed infant or the effects of the drugs on milk production. Because of the potential for (1) HIV-1 transmission (in HIV-negative infants), (2) developing viral resistance (in HIV-positive infants), and (3) adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving DOVATO. **Females and Males of Reproductive Potential:** In individuals of childbearing potential currently on DOVATO who are actively trying to become pregnant or if pregnancy is confirmed in the first trimester, assess the risks and benefits of continuing DOVATO and discuss with the patient if an alternative treatment should be considered. Pregnancy Testing: Pregnancy testing is recommended in individuals of childbearing potential before initiation of DOVATO. Contraception: Individuals of childbearing potential who are taking DOVATO should be counseled on the consistent use of effective contraception. **Pediatric Use:** The safety and efficacy of DOVATO have not been established in pediatric patients. **Geriatric Use:** Clinical trials of DOVATO did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, caution should be exercised in the administration of DOVATO in elderly patients reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30mL/min because DOVATO is a fixed-dose combination and the dosage of the individual components cannot be adjusted. If a dose reduction of lamivudine, a component of DOVATO, is required for patients with creatinine clearance <30mL/min, then the individual components should be used. Patients with a creatinine clearance between 30 and 49 mL/min receiving DOVATO may experience a 1.6- to 3.3-fold higher lamivudine exposure (AUC) than patients with a creatinine clearance ≥50 mL/min. There are no safety data from randomized, controlled trials comparing DOVATO to the individual components in patients with a creatinine clearance between 30 and 49 mL/min who received dose-adjusted lamivudine. In the original lamivudine registrational trials in combination with zidovudine, higher lamivudine exposures were associated with higher rates of hematologic toxicities (neutropenia and anemia), although discontinuations due to neutropenia or anemia each occurred in <1% of subjects. Patients with a sustained creatinine clearance between 30 and 49 mL/min who receive DOVATO should be monitored for hematologic toxicities. If new or worsening neutropenia or anemia develop, dose adjustment of lamivudine, per lamivudine prescribing information, is recommended. If lamivudine dose adjustment is indicated, DOVATO should be discontinued and the individual components should be used to construct the treatment regimen. **Hepatic Impairment:** No dosage adjustment of DOVATO is necessary in patients with mild or moderate hepatic impairment (Child-Pugh Score A or B). Dolutegravir has not been studied in patients with severe hepatic impairment (Child-Pugh Score C); therefore, DOVATO is not recommended for patients with severe hepatic impairment.

OVERDOSAGE

There is no known specific treatment for overdose with DOVATO. If overdose occurs, the patient should be monitored and standard supportive treatment applied as required. Dolutegravir: As dolutegravir is highly bound to plasma proteins, it is unlikely that it will be significantly removed by dialysis. Lamivudine: Because a negligible amount of lamivudine was removed via (4-hour) hemodialysis, continuous ambulatory peritoneal dialysis, and automated peritoneal dialysis, it is not known if continuous hemodialysis would provide clinical benefit in a lamivudine overdose event.

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EVALUATING MEMORY LOSS IN PRIMARY CARE: A NEW APPROACH

BY MORGAN INGEMANSON, PHD

How Do You Evaluate Memory Loss?

When an individual begins to show signs of memory loss, a physician's greatest challenge is often discovering the underlying cause of symptoms. Behavioral evaluations (including self-report questionnaires such as MoCA and MMSE, effort-based computerized testing, and psychological evaluations) and laboratory tests (such as APOE genotyping and biochemical labs such as blood, urine, and CSF analysis) can be useful in developing a diagnosis in cases of advanced symptom presentation1. But how useful are these tools in assessing cases of early memory loss? Are they capable of detecting dementia early, before disease advancement, so that the physician has the opportunity to implement a successful treatment intervention?

Unfortunately, gold standard assessments often struggle with discovering early stage memory loss. The diagnosis of Alzheimer's disease (AD) is delayed on average 2-3 years after symptom onset2,3, at a point in which prognosis is poor. Ample clinical research has repeatedly demonstrated that brain changes associated with AD may begin 20 or more years before symptoms appear4. If implemented during this pre-symptomatic stage, lifestyle interventions including diet, exercise, cognitive training and monitoring vascular risk can improve or maintain cognitive functioning and potentially course-correct patients headed down the road to dementia5. Sadly, the tools most often used by physicians to evaluate memory loss are unable to detect this early stage of memory loss.

Moreover, many individuals have dementia-like symptoms without the progressive brain changes of Alzheimer's disease (AD) or other degenerative brain diseases. Especially in early stages, memory loss related to dementia can be difficult to distinguish from cognitive decline caused by depression, thyroid problems, medication side effects, certain vitamin deficiencies, and even normal healthy aging6. Indeed, up to one in five patients diagnosed with probable AD during their lifetime did not have AD pathology at autopsy7.

How is it possible that current gold standard tools lack the sensitivity and objectivity needed to develop timely and accurate diagnoses for patients experiencing memory loss? It is because memory loss is a brain problem. Symptom screeners and effort-based computerized testing base conclusions off of behavior, not off of how the brain is functioning. Likewise, laboratory tests do not directly assess the main organ of interest. The impairment of memory, language, problem-solving, and other cognitive skills that characterize dementia occurs because neurons in the brain are damaged, destroyed, or dysfunctional. Shouldn't the highest standard of care for memory loss patients include a direct and objective assessment of the brain itself?

Brain-Based Biomarkers.

Biomarkers are measurable characteristics of a biological function or response that can be objectively measured and evaluated to investigate processes in health and disease. Given that an objectively brain assessment is critical in pinpointing the cause of memory loss, a number of neuroimaging diagnostic biomarkers have been identified for clinical use. These include amyloid deposition as measured by PET scan and cerebral atrophy as measured by MRI8. Unfortunately, in the case of Alzheimer's disease, these biomarkers begin to present once the disease has already begun to progress (Figure 1). Only once clinical symptoms are evident do various regions of the brain demonstrate atrophy detectible by volumetric MRI4. Moreover, from a practical perspective, these imaging techniques are expensive and/or invasive and therefore remain unavailable to the patients' first line of contact – the primary care physician.

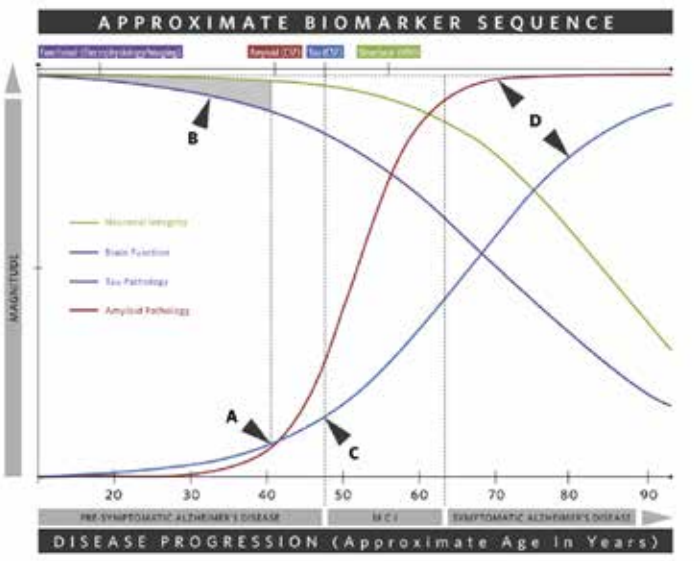


Figure 1. Depiction of the main changes across the progression of Alzheimer's disease and the sequence of associated biomarkers4. A) Tau and amyloid pathology begin. B) The shaded region indicates a window in which tau and amyloid pathology cause functional impairments that are not great enough to result in clinical symptoms. CSF changes in Aβ and tau are absent but functional biomarkers as measured by EEG and ERP are present. This early pre-symptomatic stage is the time during which the most effective treatments will be initiated and any damage may be reversed. C) Clinical symptoms become apparent. D) Clinical symptoms are progressive and severe. Various brain regions demonstrate atrophy as measured by volumetric MRI.

Electroencephalography, or EEG, involves the measurement of neural oscillations in the brain (i.e., brainwaves), and has long been established as a robust and valuable tool for investigating changes in neural functional. As opposed to techniques that measure brain structure like MRI and CT, EEG evaluates the electrical activity of the brain to reveal how the brain functions. These electrical changes can be measured during a resting state, reflecting spontaneous neural activity, and in "event-related potentials" (ERP), which reflect brain processing speed of environmental stimuli. Due to the un-intrusive, non-invasive, and inexpensive nature of EEG, it is a widely used tool for investigating brain function and neurophysiological health or disease in humans. Additionally, and of particular pertinence, a number of hallmark alterations have been noted in the EEG and ERPs of patients with dementia9.

Up to 20 years prior to the onset of symptoms, there is a window within Alzheimer's disease progression wherein tau pathology and early amyloid pathology cause impairments in brain function prior to extensive neurodegeneration (Figure 1). Although CSF changes in Aβ and tau are absent at this stage, and functional impairments are not great enough to result in clinical symptoms, clinical research has demonstrated that EEG is capable of detecting biomarkers of impaired brain function.

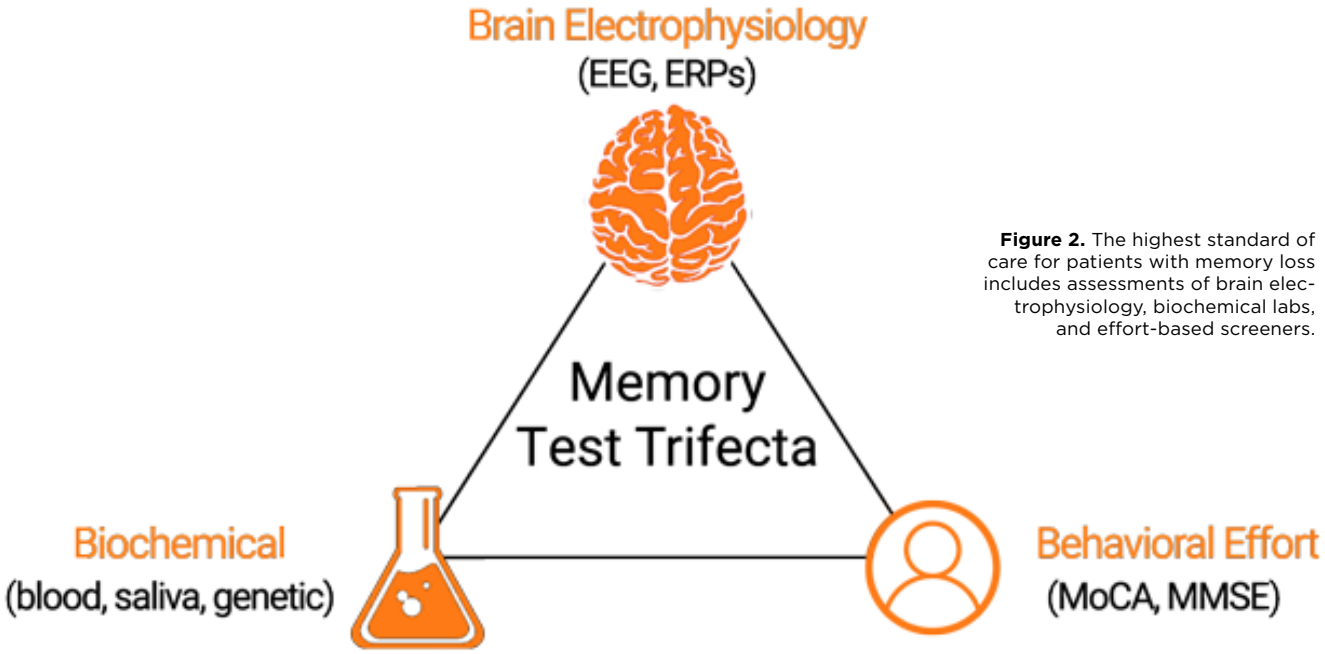


Figure 2. The highest standard of care for patients with memory loss includes assessments of brain electrophysiology, biochemical labs, and effort-based screeners.

These include spectral "slowing" as measured by quantitative EEG (qEEG), which presents as a relative increase in low frequency brainwaves, and slowed brain processing speed, as indicated by a delay in the P300b component of the ERP waveform9. It is hypothesized that the most effective treatments for AD will be initiated during this early pre-symptomatic stage of the disease, when any damage may be reversed4. Thus, the ability for a primary care physician to collect EEG data and measure these memory loss biomarkers would profoundly improve their ability to make the correct diagnosis and to also provide the prognosis of how to treat the cause.

EEG and ERP for the Primary Care Physician.
Leading research agrees that utilizing traditional clinical evaluation and biochemical labs together with other supportive diagnostic techniques such as functional neuroimaging may be necessary to substantiate the diagnosis of MCI and the subsequent risk of developing AD10 (Figure 2).

With the understanding that the highest standard of care for patients with memory loss includes brain electrophysiology evaluations, comes the need for tools that provide objective memory-related measures that guide and inform physicians in their provision of more targeted therapies. Ideally, such tools would be available in the primary care office, as this is often the first point of care for patients experiencing symptoms of memory loss. However, traditional EEG devices have remained unavailable to most doctors because of expense and complex, time-consuming data interpretation. Historically, only neurologists have had the resources and training to derive clinical significance from EEG data. Moreover, the biomarkers useful in detecting pre-clinical dementia are measured via ERP and quantitative EEG (qEEG) testing, which require sophisticated data processing and comparisons with normative database references values. ERP and qEEG biomarkers provide enhanced objectivity and sensitivity over conventional visual inspection of EEG, yet primary care and specialty physicians alike have not had access to normative database comparisons that permit this type of quantitative analysis.

Advances in data processing and analytics have led to a golden age of electrophysiology assessments. Companies like Evoke Neuroscience (www.evokeneuroscience.com) have created low-cost, easy to use systems designed specifically to suit the needs of primary care physicians. In the case of Evoke Neuroscience's eVox® System, primary care physicians now have access to these important biomarkers for memory loss to aid their diagnosis. A simple solution of integrated EEG hardware and software allows objective evaluations of brain function that can be performed by office staff. By providing these memory loss biomarkers, the eVox® System supports doctors in objectively assessing patients and may aid in recognizing pre-clinical dementia conditions, identifying the root cause of memory loss, and performing a differential diagnosis.

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3 THINGS PATIENTS REALLY WANT FROM THEIR DOCTORS

BY SUNEEL DHAND, MD

The doctor-patient interaction is the absolute core of clinical medicine. Maybe I'll go much further: it's the core of health care in general. I always try to remember, whenever I'm ever feeling frustrated with the system, the crazy bureaucracy — and of course, the debacle of our clunky electronic medical records and their data entry requirements — to separate myself from all of that when I'm face-to-face with my patient and their family. This time is priceless, it's why I went into this. The interactions and honor of serving my patients at a low point in their lives, makes it all worth it. It's where the magic of medicine happens, and is something that is untouchable by any external factor, if you choose to make it that way.

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We are already very good with our scientific knowledge and have stellar treatments at our disposal — but it's the human side that is too often forgotten.

Here are three things that patients want from that doctor-patient interaction:

1. A compassionate doctor who communicates well. A physician who understands that they are coming to them for help, shows empathy, and listens carefully to the problem. The doctor should exhibit both in their verbal and non-verbal communication, that they are fully engaged in being their doctor, who truly cares for them. There are an array of phrases and body language techniques that can be used to show empathy, all of them are very learnable, and deeply appreciated by your patients.

2. A doctor who is honest and transparent. I actually think almost all physicians are this way anyway — highly trustworthy professionals in the first place (anyone not that way, would unlikely have made it so far). Nothing but complete honesty with a sincere interest in getting the best possible outcome. Explain everything slowly, clearly and in understandable terms — as if you are talking to a family member who knows nothing about health care.

3. A non-distracted physician. Nobody wants to pour their heart out to somebody who is not fully present in the conversation. No turning around, clicking, or looking elsewhere for extended periods of time. This is patient face time, not screen time. A technique that I use, that gets very positive feedback: I actually ditch the computer completely, especially when meeting a patient for the first time. I sit opposite them, lean in, and am fully present. I jot notes down on a piece of paper on my lap. Patients love it (actually anyone would like that kind of service when they are explaining something in a professional situation, even at Home Depot!). Writing things down when face-to-face with someone, subconsciously gives a better impression that you are concentrating and mentally processing, rather than typing on a keyboard and turning at a screen. It just does.

So these are just three things that any physician should strive to do in their interaction, to give their patients the experience they deserve. It may just be another "name on the list" for us — but for patients who may have waited hours or days to see us, it's the part of their day that they will usually remember and appreciate the most.

Over my years of treating thousands of patients, seeing so many misunderstandings and poor interactions, and now being in a position where I am teaching many of these skills — I am really of the belief that what patients ask for is really not that much. We are already very good with our scientific knowledge and have stellar treatments at our disposal — but it's the human side that is too often forgotten. Sure, time is tough, and not available in abundance. But even just an extra minute or two can make a huge difference.

What I am saying here may not sound "trendy or fashionable" to lots of folks. Scroll the Twitter and LinkedIn feeds of many of our administrators and technologists, who are now dominating health care, and you'll soon see why the above is the last thing they want to hear. To lots of them, health care is all about spreadsheets and numbers, expensive new technologies, and building factory-like processes. But it really isn't, and never will be. Unfortunately too, the doctor-patient relationship is something that may even be intimidating to many administrators — because it's something that they can't "get to" or really control. It shouldn't be that way.

We are currently in a health care swamp of epic proportions, where we lose the forest for the trees. We keep moving further away from the frontlines, among a tidal wave of bureaucracy (see this chart, if you want to see the unbelievable growth of administrators versus physicians over the last 30 years). Of course, a sector as big as health care does need some oversight, rules, and regulations — but we've gone too far.

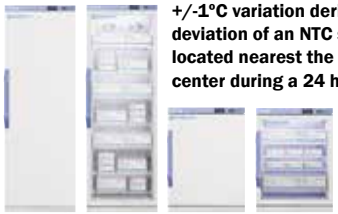
That moment when a physician sits down with their patient, is what the practice of medicine is all about, and should take front and center stage in any health care system. So Doctor, this is your time. Make the most of it and let's give patients what they deserve when we are face-to-face. Even if the rest of the world around us feels like its tumbling down.

Suneel Dhand is a physician, author and speaker. He is the Founder at DocSpeak, and Co-founder at DocsDox. He blogs at his self-titled site: suneeldhand.com

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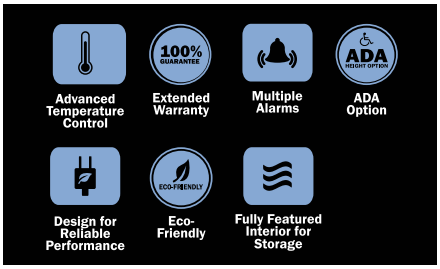
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- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing 9848

(can be combined with SUDOMOTOR into 1 full system)

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



3 SudoMotor Testing 9849

(can be combined with ANS into 1 full system)

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

Medical Device Depot Inc.

www.medicaldevicedepot.com

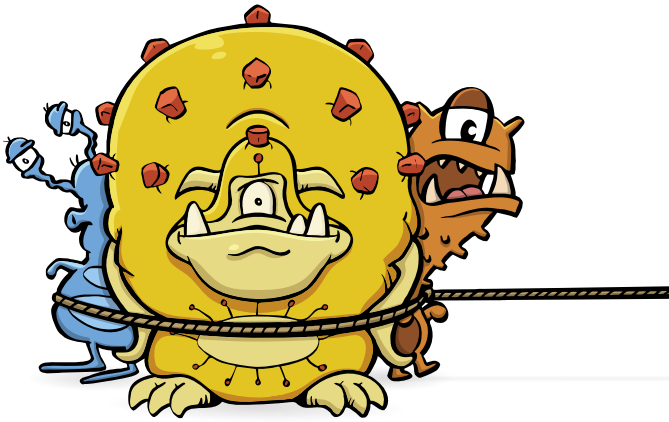
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PIONEERING DIAGNOSTICS

BIOMÉRIEUX

Round up SARS-CoV-2 and 18 other pathogens.



The new BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA)[1] covers SARS-CoV-2 detection and so much more.

Right now, SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. Testing for just SARS-CoV-2 or influenza could mean running the risk of missing the real culprit, leading to missed infections, or even coinfections. Additionally, many rapid diagnostic tests sacrifice accuracy for speed, with sensitivities oftentimes ranging from 50–70%.[2]

Now you can test for 18 common respiratory pathogens in your clinic, including SARS-CoV-2 in patients suspected of a COVID-19 infection with syndromic testing from the BioFire RP2.1-EZ Panel—now available under an FDA Emergency Use Authorization (EUA).[1,3] Syndromic testing means all it takes is one test and about 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects. What's your frontline solution for respiratory season and beyond?

To learn more, visit **biofiredx.com**



BioFire RP2.1-EZ Panel (EUA)

Overall 97.1% sensitivity and 99.3% specificity (prospective specimens)[4]

SARS-CoV-2 98.0% sensitivity and 100% specificity (archived specimens)[5]

SARS-CoV-2 100% PPA and 100% NPA (contrived specimens)[6]

BIOFIRE®

1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of invitro 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 authorization is terminated or revoked sooner. 2. http://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm 3. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration. 4. Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel. 5. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission 6. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.

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