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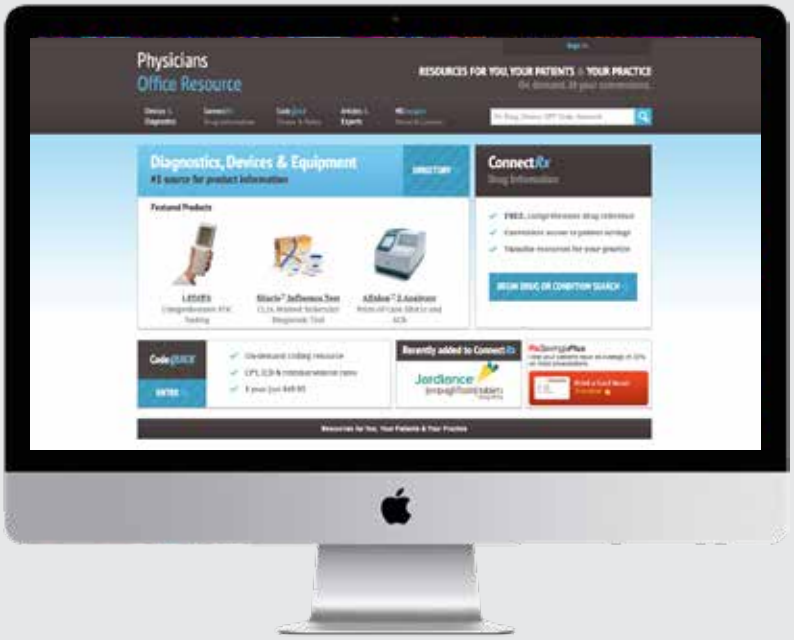


Change Healthcare?
THINK SMALLER

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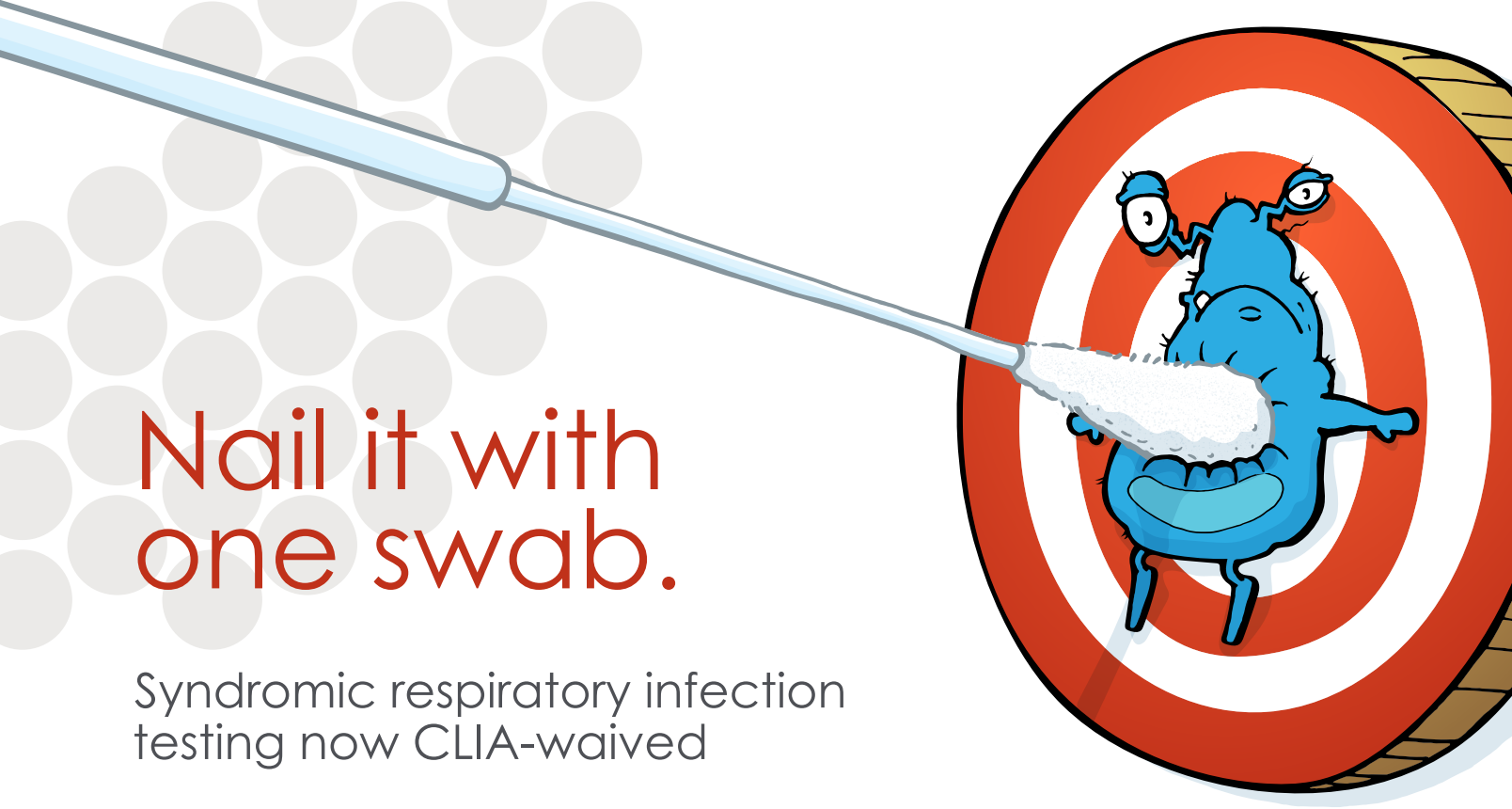
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6 Change Healthcare?

THINK SMALLER

Healthcare often works like a big, cantankerous machine. Anyone in the field knows that the actual administration of health care makes up only a small portion of what their job encompasses, as they split their time between healing, business administration, policy interpretation and whatever else might come their way. And with substantial changes to healthcare reporting and reimbursement metrics, constantly stretch the ways in which physicians can define and evaluate their own work.

16 **A Turning Point for Digital Health**

When the coronavirus finally passes, we could well look back at this crisis as a turning point for digital health. For years everyone has talked about digital health, but until the coronavirus forced patients and physicians into actually using digital health, it remained somewhat of a mystery. In this article, we'll examine more specifically how to use digital health for patients with diabetes.

20 **Strategies Necessary to Achieve Quality Waived Testing**

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) created the concept of waived tests which are defined as tests that are so simple to perform, and produce accurate results so reliably, as to render the likelihood of erroneous results negligible; and which also pose no reasonable risk of harm to the patient even if the test is performed incorrectly.



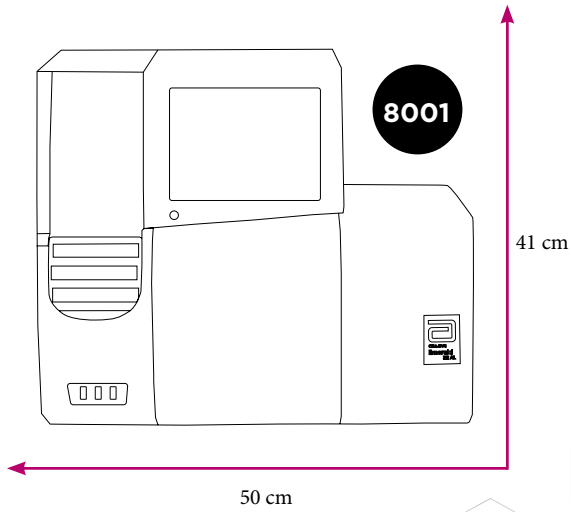
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CHANGE HEALTHCARE? THINK SMALLER

BY DYLAN CHADWICK

Healthcare often works like a big, cantankerous machine. Anyone in the field knows that the actual administration of health care makes up only a small portion of what their job encompasses, as they split their time between healing, business administration, policy interpretation and whatever else might come their way. And with substantial changes to healthcare reporting and reimbursement metrics, constantly stretch the ways in which physicians can define and evaluate their own work. In many ways, the job of the physician becomes more convoluted with modernity as new standards dictate more disparate situations for physicians to address. Adhering to evidence, maintaining patient engagement, reducing waste and preventing physician burnout now vie for physician attention with the same urgency their own patients are bringing to them.

It's the kind of situation that can make anyone feel overwhelmed, especially when tasked with the grandiose jobs like "making healthcare better and more efficient." The various routes physicians can take to enact these changes within their own practices are broad and multi-directional and even contradictory at times as practice leaders struggle to implementing global improvements from local efforts.

In a KevinMD article about physician involvement in the big healthcare change, Stephen Beeson MD states "If we are to harness the full potential of those professionals touching patients, our top-down mindset won't cut it." Essentially, he claims that a "top down" communication method in which policy and thought leaders determine healthcare goals, broadcast them and then hold their constituents accountable to them will not work in the current environment. Beeson even called the "top down health care leadership mindset" the culprit for the "Death and very spirit and behaviors that are essential to [healthcare's] transformation." He contends that physicians need to improve in relying on the power of teams to lead themselves with shared simple rules and deep mutual purposes. Rather than a system of increasingly ratcheted regulation, creating a small series of individual successes and growth patterns will create the big healthcare changes we seek.

Think Global, Act Local

Perhaps then, given health care's increasing need for improved metrics and reporting, ideas like "self government" and "think global but act local" seem antithetical or even a bit like fantasy. However, the feelings of powerlessness that many physicians feel, coupled with the increasing shifts in workload, policy and dynamic, it's increasingly important for them to re-evaluate that which they can directly control and see the big door that the small hinge can swing. In some cynical kind of way, physicians really are powerless to the outside changes affecting healthcare. When they take their efforts inward to their own practices, they'll surely find that the big changes demanded by the global health community can start right in their own practice.

Your Team, Your Rules

Every practice is different. From the size of the staff to the demographics of the patient base, there's nuances and factors that affect every practice differently. As such, it's crucially important for physicians to establish team cohesion as best defined by the standards and factors of their particular practice in addition to large scale "top-down" mandates.

Well-defined, shared simple team rules go a long way in establishing a unified work approach and helping productivity across the board. Obviously, the specific practices and goals of each team will vary, but by consciously developing a team leading approach that is decidedly local, physicians ensure a measurable campaign with which to roll out more global productivity and efficiency goals. It's a move that often results in higher morale, that which results from solid cohesion and clear communication. Then the productivity stats follow.

The Healer Must be Healed

It's a well worn expression but it's far from trite. If physicians are the tool that facilitates good health for patients and the world at large, then they must constantly be in their best shape, both physically and mentally to do it. Physicians should take a proactive approach to their personal health, not just in terms of diet, exercise and internal workings but also in the work-life



balance model. Physicians who take time away from medicine at appropriate times, in order to recharge and heal when they return, are better physicians in the long run. They're not sidelined by physician burnout, an ailment that comes on without much warning, is difficult to detect and has far-reaching complications and negative effects on one's ability to practice. An ounce of prevention equals a pound of cure, and a proactive approach to physician's personal health will keep physicians strong and versatile, able to roll with the many punches enacted by outside policy and circumstance.

Not All Software is Created Equal

One cottage industry surrounding the rise of increased health care metrics are the various data encryption services and electronic health record softwares marketed to medical practices. Obviously, in 2020 NOT using electronic software is a luddite liability, but practices would be smart to keep their software updated on their own terms and not feel pressure to adopt "popular" software just because it's pitched to them. Some small practices may find that the increased variables and complexity of certain softwares may not suit their practice as well as a smaller, simpler program with less versatility but more long-term stability.

Additionally, implementing new software can present holdups in a practice's workflow as staff must be trained on its various processes and protocols, often times having to re-learn a completely new system. While it's important for security reasons to keep software updated, constantly changing software of updating to the new hot program being foisted on practices at the time presents hold ups and hijacks on productivity that (ironically) complicate the process that the software purports to streamline.

Ultimately, the complicated "outside" forces that make health care a difficult landscape to traverse won't stop. It's realistic to assume such, not cynical. In that sense, why spend inordinate amounts of time and energy focusing on the volatilities of the modern health/business care puzzle? Focusing inward, creating sufficient practices with self-sustaining goals and internal measurable successes will yield the same results with far less administrative headache.

—

References

Beeson, Stephen, MD. "To Make Big Health Care Changes, Think Small."
KevinMD.com. KevinMD, 09 May 2016. Web. 16 May 2016.



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*"Long-acting" was defined as efficacy measured over a 12-week period following a 225 mg x 3 (675 mg) SQ dose.[1]

CGRP: calcitonin gene-related peptide; **SQ:** subcutaneous.

INDICATION

AJOVY is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please see the Brief Summary of the Prescribing Information on the adjacent page.

Reference: 1. AJOVY® (fremanezumab-vfrm) injection Current Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.

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teva

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR AJOVY® (fremanezumab-vfrm) injection, for subcutaneous use

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- 225 mg monthly, or
- 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions

AJOVY is for subcutaneous use only.

AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique *[see Instructions for Use in full Prescribing Information]*:

- Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 24 hours or longer.
- Follow aseptic injection technique every time AJOVY is administered.
- Inspect AJOVY for particles or discoloration prior to administration. Do not use if the solution is cloudy, discolored, or contains particles.
- Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
- Do not co-administer AJOVY with other injectable drugs at the same injection site.

4 CONTRAINDICATIONS

AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration.

If a hypersensitivity reaction occurs, consider discontinuing AJOVY, and institute appropriate therapy.

6 ADVERSE REACTIONS

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

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

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

The safety of AJOVY was evaluated in 2512 patients with migraine who received at least 1 dose of AJOVY, representing 1279 patient-years of exposure. Of these, 1730 patients were exposed to AJOVY 225 mg monthly or AJOVY 675 mg quarterly for at least 6 months, 775 patients for at least 12 months, and 138 patients for at least 15 months. In placebo-controlled clinical trials (Studies 1 and 2), 662 patients received AJOVY 225 mg monthly for 12 weeks (with or without a loading dose of 675 mg), and 663 patients received AJOVY 675 mg quarterly for 12 weeks. In the controlled trials, 87% of patients were female, 80% were White, and the mean age was 41 years.

The most common adverse reactions in the clinical trials for the preventive treatment of migraine (incidence at least 5% and greater than placebo) were injection site reactions. The adverse reactions that most commonly led to discontinuations were injection site reactions (1%). Table 1 summarizes adverse reactions reported in the 3-month placebo-controlled studies (Study 1 and Study 2), and the 1-month follow-up period after those studies.

Table 1: Adverse Reactions Occurring with an Incidence of At Least 2% for Either Dosing Regimen of AJOVY and At Least 2% Greater Than Placebo in Studies 1 and 2

Adverse Reaction	AJOVY 225 mg Monthly (n=290) %	AJOVY 675 mg Quarterly (n=667) %	Placebo Monthly (n=668) %
Injection site reactions[a]	43	45	38

[a] Injection site reactions include multiple related adverse event terms, such as injection site pain, induration, and erythema.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose test results were positive for antibodies to AJOVY in specific assays.

In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 1701 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 1.6% of patients (30 out of 1888). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose samples. Although these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development *[see Animal Data]*. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg.

Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg).

Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation

Risk Summary

There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-004.

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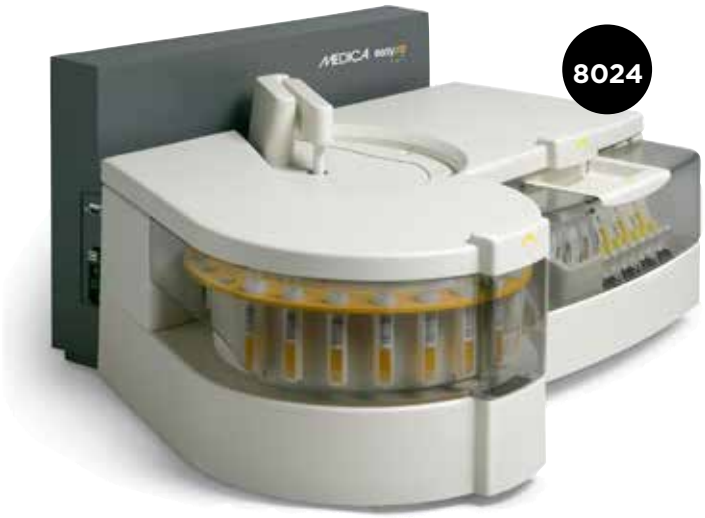
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FEATURE

A turning point for DIGITAL HEALTH

DAVID KLIFF, THE DIABETIC INVESTOR

When the coronavirus finally passes, we could well look back at this crisis as a turning point for digital health. For years everyone has talked about digital health, but until the coronavirus forced patients and physicians into actually using digital health, it remained somewhat of a mystery. In this article, we'll examine more specifically how to use digital health for patients with diabetes.

One thing we don't do is review the many digital health apps or web sites. What we can say without being too geeky is these systems have functioned well, continue to improve, and are patient/doctor friendly. Based on the discussions, we've had some physicians don't have a choice in which system they use as their hospital or practice group has decided for them. To us, it doesn't matter which method is used heck we know of people using FaceTime for virtual consults.

The digital or virtual consult isn't that different than face to face consult in that you can only do so many a day, and the more prepared both you and the patient are, the more compelling these consults are. Thankfully for your patients with diabetes, getting prepared has never been easier as there are a plethora of apps and devices which, when adjusted by the patient, can seamlessly share information with your office.

The most common of these tools are continuous glucose monitors, CGM, which, as the name implies, measure a patient's glucose on a continuous basis. The two most prevalent systems come from Dexcom and Abbott. The G6 from Dexcom and Libre from Abbott (as we write the Libre2 is awaiting FDA approval) both collect glucose data and can then share this data with your office. These systems are patient-friendly, accurate, and reliable. Better still, both eliminate the need for any fingersticks.

Dexcom offers patients the Clarity app, which contains several reports which also can be shared. Abbott offers the LibreLink app, which does the same thing. Both apps make it easy to share glucose data, which can be as basic or detailed as you want.

In addition to glucose data, your patients with diabetes can also share other valuable pieces of data thanks to device connectivity. Today's insulin pumps offer similar reporting capabilities as well as some connected insulin pens such as the InPen from Companion Medical, which can share insulin dosing information. In the future, all the major insulin companies Lilly, Novo Nordisk, and Sanofi plan on offering connected insulin pens or connected cap covers which work with the current crop of disposable insulin pens.

Currently, Lilly has a connected cap cover awaiting FDA approval, while Novo has a durable connected pen similar to the InPen in use overseas. Novo has plans to introduce a connected cap cover here in the US sometime next year, given the prevalence of disposable insulin pens used in the US. Sanofi, for



their part, is following Novo's lead, developing both connected durable pens and connected cap covers used with disposable insulin pens.

All of the insulin companies have agreements/partnerships with Dexcom and Abbott so that their apps collect not only insulin dosing data but also glucose data. These apps even include insulin dosing algorithms that perform the data analytics and then make insulin dosing recommendations to the patient.

Even with all this connectivity, some areas have not yet reached the digital stage. The most obvious being blood panels. This data can be easily shared once obtained, but the patient still must visit a lab or have these blood draws performed in an office setting. Therefore we would highly recommend these panels be done before a virtual consult.

Another area that has yet to go digital is therapy adherence. Several apps remind patients to take their pills, and many allow a patient to enter when they do so manually. Currently, there are no apps or tools we know of which track when or if patients are taking their medications as prescribed.

The same can said for patients following GLP-1 therapy. While insulin pens, both durable and disposable, are becoming digital, we are not aware of any GLP-1 pen, which is becoming digital.

For these reasons, glucose data tracked by a CGM becomes even more valuable as it can be deep insights into a patient's therapy adherence. As one physician put it since the technology is not available to track non-injectable therapy adherence, CGM data becomes even more helpful. As we all know, there are only so many variables that impact a patient's diabetes. CGM data allows for a more constructive consult with the patient.

Given the detail available in the reports generated by the CGM systems combined with a few simple questions to the patient, you can determine when or if the patient is taking their medications. As another physician noted, once you have the data, the questions asked serve as a process of elimination. Let's be honest here there are only so many reasons why a patient is not achieving reasonable control, CGM data combined with such simple questions allows you to get at the root cause.

The best news of all is that these CGM systems have become more affordable and widely reimbursed, allowing for greater patient adoption. Even better, both Dexcom and Abbott offer high-quality patient support, so you or your staff don't waste time training the patient on how to use the system and the apps that share data and produce reports. As we all know, time is not a renewable resource, and whether it's done virtually or in person, you cannot afford to waste time.



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*Results after 10-minute incubation period for Flu A+B and RSV; after 5-minute incubation period for Group A Strep
†RSV- Respiratory Syncytial Virus

References:
1. BD Veritor System for Rapid Detection of Flu A+B, CLIA-waived kit package insert, 8087667 (14) 2018-06.
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FEATURE



STRATEGIES NECESSARY TO ACHIEVE QUALITY WAIVED TESTING

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

Introduction

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) created the concept of waived tests which are defined as tests that are so simple to perform, and produce accurate results so reliably, as to render the likelihood of erroneous results negligible; and which also pose no reasonable risk of harm to the patient even if the test is performed incorrectly. Thus, these tests are exempt from federal requirements for personnel qualification, training, and competency assessment; quality control (except as specified by the manufacturer), proficiency testing, quality assessment, and the need for routine inspection

As a result, laboratory professionals have long expressed concern about the quality of testing performed in these laboratories. This concern has only grown with the rapid proliferation of waived tests, along with point of care /remote testing sites.

Quality Concerns

As a response to these concerns, both CMS and the CDC conducted random surveys of waived laboratories several years after CLIA 88 was enacted. These labs had significant quality issues, including the lack of available written procedures; adequate personnel training, quality control performed as required; also, the lack of a proper attention to reagent expiration dates and storage requirements; and the failure to enter test results into electronic medical records[1]. Although not usually specified in the product insert (and therefore not a

CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices.

Among the waived laboratories surveyed, the study also found[2]:
- High staff turnover
- Lack of formal laboratory education
- Limited training in test performance and quality assessment

Strategies to Address These Concerns
Competent Management and Organization
To be effective, efforts to achieve quality waived testing through good lab practice must start even before the testing process, all the way back to assessing the laboratory structure, organization, and purpose. These include:

Commitment to Constant Oversight of the Testing Process
In POLs, this might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing.

Anticipating and Addressing Personnel Needs
Personnel competency and turnover are important factors affecting the quality and reliability of waived testing results. While there are no CLIA requirements for personnel performing waived testing, all applicable state or local personnel regulations must be met.

Personnel issues to consider include assessment of present staffing levels and training, to ascertain whether employees have sufficient time and skills to reliably perform all activities needed for testing.

Personnel Training

Personnel should be trained and competent in each test they will perform before reporting patient results. It is the responsibility of the laboratory director or other supervisory staff to ensure that this training has occurred, along with proper documentation of these efforts.

Competency Assessment

To ensure testing procedures are performed consistently and accurately, periodic evaluation of competency is recommended, with retraining, as needed, on the basis of results of the competency assessment.

Development and Maintenance of Procedure Manuals
It is good laboratory practice to develop written policies and procedures so that responsibilities and testing instructions are clearly described for the testing personnel. Written test procedures also form the basis of training and evaluation of testing personnel. These procedures should be derived from the manufacturer's instructions, and include directions for specimen collection and handling, quality control, test and reagent preparation, and instructions for test performance, interpretation, and reporting.

New testing procedures should be reviewed, signed, and dated by the laboratory director before incorporating them into the procedure manual. The manual should be updated as tests or other aspects of the testing service change and should be reviewed by the director whenever changes are made. When procedures are no longer used, the date of discontinuance should be noted, and they should be removed from the manual. The manual should always be readily available to all testing personnel.

Maintenance of Complete and Accurate Documents and Records
Proper documentation is necessary for monitoring and assessing test performance, identifying and resolving problems that could affect patient testing, retrieving and verifying information, and maintaining adequate patient and personnel records. Log books or electronic systems can be used for maintaining and tracking information. In some cases, records might be part of the patient's medical chart.

Performance of Quality Assessment

Good laboratory practices can be expanded to include activities to evaluate and improve the quality of waived site testing, utilizing both internal and external quality assessment activities. Results from these assessment activities should be documented and evaluated, noting any irregularities and the actions taken to resolve problems or improve processes or procedures.

Follow Best Practices During Testing

The Pre-analytic phase[3]
Test orders
Confirm that the written test order is correct. If there is a question, check with the ordering clinician before proceeding.

Patient identification
Use two unique identifiers to ensure accurate identification of the patient before the specimen is collected. Names can be similar and lead to confusion, therefore use birth dates, middle initials, patient identification numbers or other means to ensure correctness.

Pretest instructions and information
Some tests require special preparation on the patient's part (e.g. fasting), or that the patient collect the specimen (e.g. urine or stool). Provide the patient with pretest instructions when appropriate, and verify that patients have received and understood the instructions before collecting or accepting the specimen

Specimen collection and handling
The product insert provides details on proper collection, handling and storage of patient specimens. Specimens need to be adequately labeled to prevent mix-up. Always label specimens as soon as they are collected with pertinent patient information. Labeling should also include the date and time of collection and identification of the collector.

The Analytic Phase[4]

Quality Control (QC)
Quality control provides assurance that the test system has performed as expected, and alerts the user when problems occur

which may affect patient results; these can be problems due to operator error, reagent or test kit deterioration, instrument malfunction or improper environmental conditions.

If quality control testing fails to perform as expected, patient testing should not be performed or results should not be reported until the problem is identified and corrected. QC test results should be recorded and monitored. Records of control results should be periodically reviewed by the person responsible for testing oversight to detect shifts or changes in performance over time which may affect patient results.

Test Performance
Follow the steps in the test procedure exactly as described in the manufacturer's product
insert and /or the written procedures.

Results Interpretation.
Results can be recorded directly in a patient's chart, in log books, or on a separate report form. Interpretation of the results should be in accordance with instructions in the product insert.

Resolving problems
If a test result is not acceptable or requires repeat testing (e.g., out of range or invalid), record the initial result, noting it was unacceptable, take steps necessary to resolve the problem, then repeat the test and record the correct result. Good laboratory practice includes recording what happens, whether acceptable or not, and what is done to correct problems encountered during testing. Results should not be reported until the problem is resolved. Follow the steps in the product insert to resolve problems with the test results. If repeat testing does not resolve the problem, contact the manufacturer or technical representative.

The Post-analytic phase[5]:
Reporting Test Results
Patient reports should be legible and reported in a timely manner to the appropriate person. All verbal reports of test results should be documented and followed by a written report. Critical values require immediate notification of the clinician, and procedures should be in place to ensure documentation of these values along with the time of notification of the proper medical personnel.

Confirmatory testing
The product insert should explain when additional testing is needed to confirm a waived test result or when the test is to be used as part of a multi-test algorithm (e.g. throat culture needed to confirm a negative result for rapid group A strep antigen). There should be written policies and procedures to ensure that all confirmatory and supplemental testing is performed when needed. When collecting specimens for referral to another laboratory, the instructions provided by the reference laboratory must be followed, and the appropriate request form completed.
Maintaining records of referred testing
Important for patient care and follow-up. Logs and other records should have sufficient information to track and retrieve the test results and reports, such as:
- Information linking the referred specimen to patient identification.
- The name and contact information for the referral laboratory.
- The test name and date referred.
- Complete test results and the date received.
- The date the final report is issued.

A designated employee should be responsible for ensuring that all tests ordered from a referral laboratory are returned and charted appropriately for review by the ordering clinician.

Conclusion

The findings of multiple surveys of sites performing waived testing throughout the United States have shown widespread lapses in quality. These studies highlight the need additional education, training and planning related to waived testing for Certificate of Waiver laboratory directors and testing personnel.

Irwin Z. Rothenberg is a Technical Writer/Quality Advisor for 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.

Endnotes
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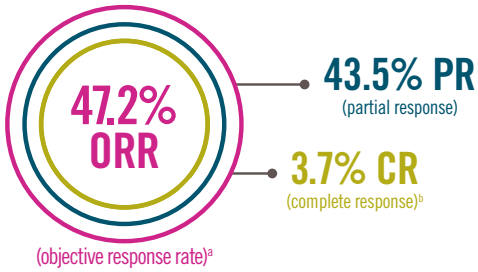
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A breakthrough for patients with advanced CSCC[1]

LIBTAYO®, a programmed death receptor-1 (PD-1) inhibitor, is the first and only FDA-approved therapy indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation[1]



ORR: 51 of 108 patients; 95% confidence interval, 37.5%, 57.1%.[1,2]

61% of responders (31 of 51) reached a duration of response (DoR) of ≥6 months[1,2,a,c]

Median DoR not reached (range: 1-15.2+ months)[1-3,a,c]

[a] At time of data cutoff; based on a combined analysis of Studies 1423 and 1540, which were single-arm, open-label, multicenter, nonrandomized, multicohort studies. Median duration of follow-up was 8.9 months.[1] See additional study design details below.

[b] Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1]

[c] Group 2 patients (locally advanced CSCC; cemiplimab-rwlc 3 mg/kg every 2 weeks) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (metastatic CSCC; cemiplimab-rwlc 350 mg every 3 weeks) from Study 1540 are excluded from the efficacy analysis set.[2]

- **Study 1423** was an open-label, multicenter, nonrandomized, multicohort study that included a total of 26 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation. Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 48 weeks. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- **Study 1540**—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included a total of 137 patients with metastatic CSCC or locally advanced CSCC who were not candidates for curative surgery or curative radiation.[1,2,4] Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 96 weeks or 350 mg LIBTAYO every 3 weeks for up to 54 weeks.[1,3] Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1]
- The major efficacy outcome measures were confirmed ORR, as assessed by independent central review (ICR), and ICR-assessed DoR.[1]
- Studies 1423 and 1540 excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; a history of solid organ transplant; prior treatment with PD-1/programmed death ligand 1 (PD-L1) blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or Eastern Cooperative Oncology Group Performance Status ≥2.[1]
- The recommended dose of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-mediated pneumonitis: Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated colitis: Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg/day or equivalent. Colitis resolved in 80% of patients. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated hepatitis: Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated endocrinopathies: Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO demonstrated meaningful tumor reduction in clinical trial patients[1,2]

Partial responses*

These are examples from the 47.2% of patients (43.5% PR,† 3.7% CR‡) who had an objective response (defined as PRs + CRs) in clinical trials. Individual patient responses may vary.

Locally advanced CSCC Not a candidate for curative surgery or curative radiation

History
- 70-year-old male
- Auricular lesions§

Outcomes
- Best overall response: PR per WHO Criteria by independent central review
- Best percent change in target lesion(s): –91.9

Screening | **After 8 weeks** | **After 32 weeks**



Metastatic CSCC

History
- 66-year-old male
- Clavicular lesions

Outcomes
- Best overall response: PR per RECIST 1.1 by independent central review
- Best percent change in target lesion(s): –71.1

Screening | **After 8 weeks** | **After 48 weeks**



*Results as of data cutoff. Group 2 patients (laCSCC; cemiplimab-rwlc 3 mg/kg Q2W) who started treatment less than 9 months prior to the data cutoff date and all Group 3 patients (mCSCC; cemiplimab-rwlc 350 mg Q3W) from Study 1540 are excluded from the efficacy analysis set.[2]

† Partial response is defined as a decrease of 30% or greater in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. Partial response of externally visible disease is defined as a decrease of 50% or greater in the sum of products of perpendicular longest dimensions of target lesions, per WHO Criteria. Responses had to be maintained for at least 4 weeks.[2]

‡ Complete response is defined as disappearance of all target lesions for at least 4 weeks. Only includes patients with complete healing of prior cutaneous involvement; locally advanced CSCC patients in Study 1540 required biopsy to confirm CR.[1,2]

§ This patient also had cranial lesions that were included in the calculation of best percent change in target lesion(s). Those images are not included here.[2]

laCSCC, locally advanced cutaneous squamous cell carcinoma; mCSCC, metastatic cutaneous squamous cell carcinoma; Q2W, every 2 weeks; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; WHO, World Health Organization.

See more patient profiles at LIBTAYOhcp.com.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

Immune-mediated nephritis with renal dysfunction: Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated dermatologic adverse reactions: Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy
- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various Grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse reactions

- Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in ≥2% of patients were cellulitis, sepsis, pneumonia, pneumonitis, and urinary tract infection. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection, and fatigue
- LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea

Use in specific populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Data on file. Regeneron Pharmaceuticals Inc. **3.** Migden MR et al. *N Engl J Med.* 2018;379(4):341-351. **4.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. Clinicaltrials.gov. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Published May 3, 2016. Updated January 14, 2019. Accessed June 10, 2019.

To learn more about LIBTAYO, speak with your sales representative or visit LIBTAYOhcp.com.

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) injection, for intravenous use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

LIBTAYO is a monoclonal antibody that belongs to a class of drugs that binds to the programmed death receptor-1 (PD-1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response with the potential for breaking of peripheral tolerance and induction of immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not be inclusive of all possible immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Early identification and management are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions *[see Dosage and Administration (2.2)]*. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over one month *[see Dosage and Administration (2.2)]*. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-Mediated Pneumonitis

Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%) and Grade 2 (1.3%) *[see Adverse Reactions (6.1)]*. Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg per day or equivalent. Pneumonitis resolved in 62% of patients.

Immune-Mediated Colitis

Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg per day or equivalent. Colitis resolved in 80% of patients.

Immune-Mediated Hepatitis

Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%) *[see Adverse Reactions (6.1)]*. Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg per day or equivalent. Hepatitis resolved in 64% of patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%), and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*.

Hypophysitis

Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of one patient with Grade 3 hypophysitis.

Hypothyroidism

Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%). No patients discontinued hormone replacement therapy.

Hyperthyroidism

Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%). Hyperthyroidism resolved in 38% of patients.

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%). Type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients.

Immune-Mediated Nephritis with Renal Dysfunction

Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*. Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg per day or equivalent. Nephritis resolved in all patients.

Immune-Mediated Dermatologic Adverse Reactions

Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg per day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO *[see Adverse Reactions (6.1)]* or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Neurological: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome / myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

Cardiovascular: Myocarditis, pericarditis, vasculitides

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis

Musculoskeletal and Connective Tissue: Myositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Hematological and Immunological: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

5.2 Infusion-Related Reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO *[see Adverse Reactions (6.1)]*. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction *[see Dosage and Administration (2.2)]*.

5.3 Embryo-Fetal Toxicity

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling.

- Severe and Fatal Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

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

The data described in WARNINGS AND PRECAUTIONS reflect exposure to LIBTAYO in 534 patients in two open-label, single-arm, multicohort studies (Study 1423 and Study 1540), including 98 patients with metastatic (nodal or distant) CSCC, 65 patients with locally advanced CSCC, and 371 patients with other advanced solid tumors. LIBTAYO as a single agent or in combination with chemotherapy or radiation was administered intravenously at doses of 1 mg/kg every 2 weeks (n=27), 3 mg/kg every 2 weeks (n=446), 3 mg/kg every 3 weeks (n=12), 10 mg/kg every 2 weeks (n=6), 200 mg every 2 weeks (n=20) or 350 mg every 3 weeks (n=23). Among the 534 patients, 38% were exposed for ≥6 months and 16% were exposed for ≥12 months.

The data described below reflect exposure to LIBTAYO in 163 patients with advanced CSCC (metastatic or locally advanced disease) in Study 1423 and Study 1540. Patients received LIBTAYO 1 mg/kg every 2 weeks (n=1), 3 mg/kg every 2 weeks (n=139) or 350 mg every 3 weeks (n=23) as an intravenous infusion until disease progression, unacceptable toxicity, or completion of planned treatment. The median duration of exposure was 20 weeks (3 days to 1.4 years).

The safety population characteristics were: median age of 71 years (38 to 96 years), 85% male, 96% white, and ECOG performance score (PS) of 0 (44%) or 1 (56%).

The most common adverse reactions reported in at least 20% of patients were fatigue, rash and diarrhea. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection and fatigue. LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness. Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in at least 2% of patients were cellulitis, sepsis, pneumonia, pneumonitis and urinary tract infection.

Table 1 summarizes the adverse reactions that occurred in ≥10% of patients and Table 2 summarizes Grade 3 and 4 laboratory abnormalities worsening from baseline in ≥1% of patients receiving LIBTAYO.

Table 1: Adverse Reactions in ≥10% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Adverse Reactions	LIBTAYO N=163	
	All Grades %	Grade 3-4 %
Skin and Subcutaneous Tissue		
Rash*	25	1.2
Pruritus†	15	0
Gastrointestinal		
Diarrhea‡	22	0.6
Nausea	19	0
Constipation	12	0.6
General and Administration Site		
Fatigue§	29	2
Musculoskeletal and Connective Tissue		
Musculoskeletal pain#	17	3
Metabolism and Nutrition		
Decreased appetite	10	0

* Rash is a composite term that includes rash maculopapular, rash, dermatitis, rash generalized, dermatitis bullous, drug eruption, erythema, rash erythematous, rash macular, rash pruritic, and skin reaction.
† Pruritus is a composite term that includes pruritus and pruritus allergic.
‡ Diarrhea is a composite term that includes diarrhea and colitis.
§ Fatigue is a composite term that includes fatigue and asthenia.
# Musculoskeletal pain is a composite term that includes: musculoskeletal pain, back pain, myalgia, neck pain, pain in extremity.

Table 2: Grade 3 or 4 Laboratory Abnormalities Worsening from Baseline in ≥1% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Laboratory Abnormality	Grade 3-4 (%)†
Chemistry	
Increased aspartate aminotransferase	3
Increased INR	2
Hypoalbuminemia	1
Hematology	
Lymphopenia	7
Anemia	2
Electrolytes	
Hypophosphatemia	4
Hyponatremia	3
Hypercalcemia	1

† Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to cemiplimab-rwlc in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Anti-drug antibodies (ADA) were tested in 398 of 534 patients who received LIBTAYO and the incidence of cemiplimab-rwlc treatment-emergent ADAs was 1.3% using an electrochemiluminescent (ECL) bridging immunoassay; 0.3% were persistent ADA responses. In the patients who developed anti-cemiplimab-rwlc antibodies, there was no evidence of an altered pharmacokinetic profile of cemiplimab-rwlc.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. There are no available data on the use of LIBTAYO in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death *(see Data)*. Human IgG4 immunoglobulins (IgG4) are known to cross the placenta; therefore, LIBTAYO has the potential to be transmitted from the mother to the developing fetus. Advise 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

Animal reproduction studies have not been conducted with LIBTAYO to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering LIBTAYO during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to cemiplimab-rwlc may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of cemiplimab-rwlc in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO *[see Use in Specific Populations (8.1)]*.

Contraception

LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Females

Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

8.4 Pediatric Use

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

8.5 Geriatric Use

Of the 163 patients with metastatic and locally advanced CSCC who received LIBTAYO in clinical studies, 72% were 65 years or older and 37% were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

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- Reimburses $170/test using 3 CPT codes
- Provides a 1 page summary up to a full 24 page comprehensive report

8058



2 SUDOMOTOR TESTING (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)

8059



3 ALLERGY TESTING

- Turn Key, comprehensive system
- 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
- 2 Minutes to apply, 15 minutes to show results
- Reimburses average $270 - $350/test, costs ~ $100/test (antigens/applicators)
- Options for Immunotherapy Treatment

8060



4 NEURO-COGNITIVE TESTING

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

8061

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From Abbott

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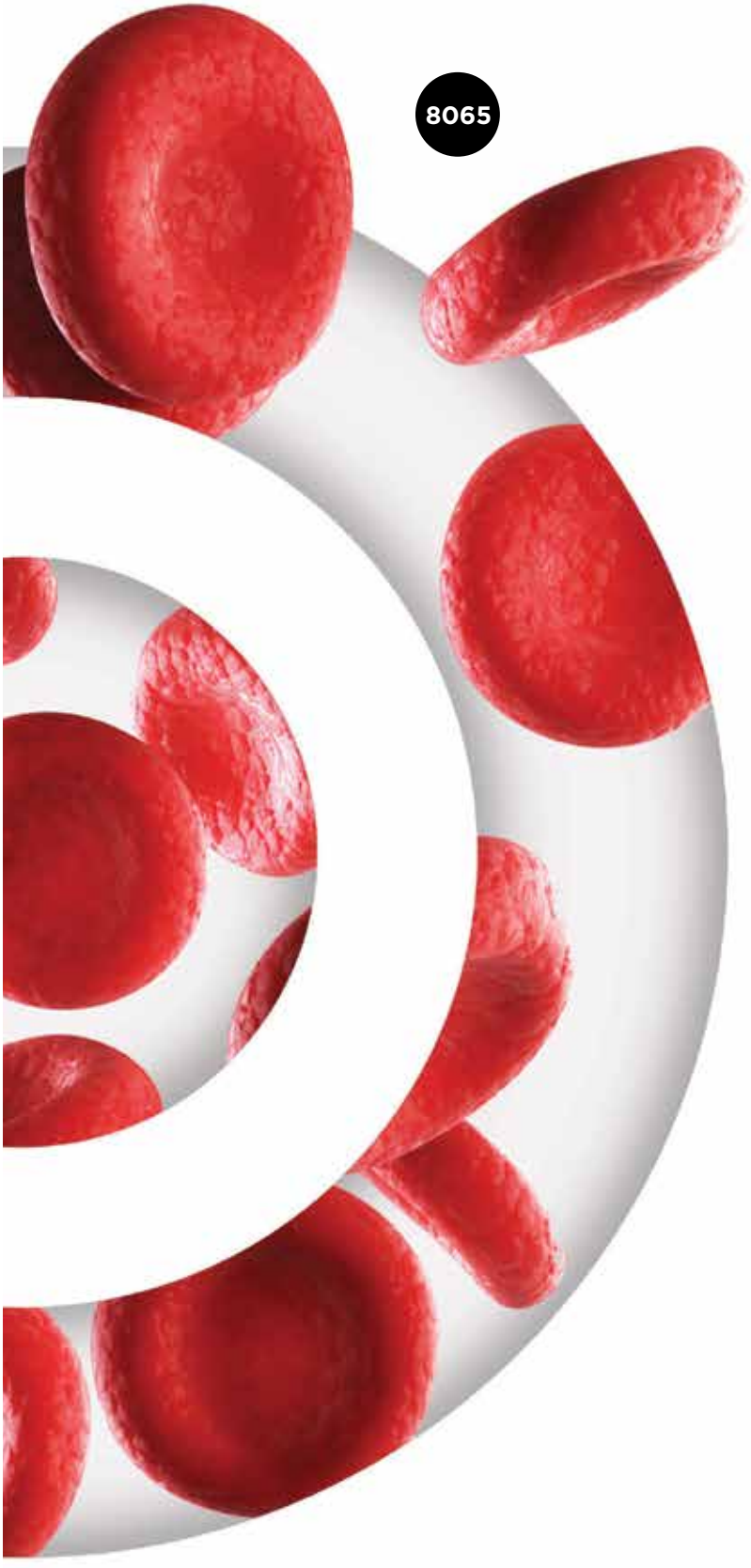
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as evaluated in a 2-year CVOT.[2]

Ozempic® is not indicated for reduction in major adverse CV events (MACE).

SUSTAIN 6: A 2-year, randomized, multinational, double-blind, placebo-controlled, parallel-group CV safety trial that was designed to assess noninferiority of Ozempic® vs standard of care by excluding the preapproval noninferiority margin of 1.8. A total of 3297 adult patients with type 2 diabetes and high risk of CV events were randomized based on evidence of CV disease, insulin treatment, and renal impairment to once-weekly Ozempic® 0.5 mg (n=826), Ozempic® 1 mg (n=822), or placebo (n=1649) in addition to standard of care treatments such as oral antidiabetic treatments, insulin, antihypertensives, diuretics, lipid-lowering therapies, and antithrombotic medication at investigator discretion. The primary composite endpoint was the time from randomization to first occurrence of a MACE, defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.[3]

Indication and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg or 1 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Ozempic® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not a substitute for insulin. Ozempic® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.**
- **Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.**

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known hypersensitivity to semaglutide or to any of the product components.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.

  Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

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In a 40-week trial, in patients on metformin, for each dose comparison

Ozempic® was superior to Trulicity® in A1C and weight reduction[1]

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg



Ozempic® outperformed Trulicity® in reducing A1C[1]

–1.4% with **Ozempic® 0.5 mg** (Baseline: 8.3%) vs
–1.1% with **Trulicity® 0.75 mg** (Baseline: 8.2%); *P*=0.002

–1.6% with **Ozempic® 1 mg** (Baseline: 8.2%) vs
–1.3% with **Trulicity® 1.5 mg** (Baseline: 8.2%); *P*=0.0004



Secondary endpoint

Ozempic® demonstrated superior body weight reduction vs Trulicity®[1]

Ozempic® is not indicated for weight loss.

–9.3 lb with **Ozempic® 0.5 mg** (Baseline: 213 lb) vs
–4.6 lb with **Trulicity® 0.75 mg** (Baseline: 211 lb); ETD=–4.7 lb (95% CI; –6.5, –2.9)

–12.8 lb with **Ozempic® 1 mg** (Baseline: 211 lb) vs
–6.2 lb with **Trulicity® 1.5 mg** (Baseline: 206 lb); ETD=–6.7 lb (95% CI; –8.5, –5.0)

SUSTAIN 7: A 40-week, multinational, multicenter, randomized, open-label, four-armed, pair-wise, active-controlled, parallel-group trial to compare the efficacy and safety of Ozempic® vs dulaglutide. A total of 1201 adult patients with type 2 diabetes inadequately controlled on metformin were randomized to receive Ozempic® 0.5 mg (n=301), Ozempic® 1 mg (n=300), dulaglutide 0.75 mg (n=299), or dulaglutide 1.5 mg (n=299) once weekly. The primary endpoint was mean change in A1C from baseline at Week 40. Secondary endpoints included mean change in body weight at Week 40 and proportion of patients achieving A1C <7% at Week 40. Results based on a sensitivity analysis of retrieved dropout population.[1]

Learn more about Ozempic® and the CVOT at ***OzempicPro.com***.

- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia:** The risk of hypoglycemia is increased when Ozempic® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin.
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Ozempic®.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- The risk of hypoglycemia may be lowered by a reduction in the dose of the secretagogue or insulin.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Please see Brief Summary of Prescribing Information on following pages.

GLP-1 RA=glucagon-like peptide-1 receptor agonist; CV=cardiovascular; CVOT=cardiovascular outcomes trial; ETD=estimated treatment difference; CI=confidence interval.

References: 1. Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. **2.** Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017. **3.** Marso SP, Bain SC, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med.* 2016;375(19):1834-1844.

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5mg|1mg

OZEMPIC® (semaglutide) injection

Rx Only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined *[see Warnings and Precautions]*. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Contraindications]*. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC® *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: OZEMPIC® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: OZEMPIC® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans *[see Warnings and Precautions]*. OZEMPIC® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis *[see Warnings and Precautions]*. OZEMPIC® is not a substitute for insulin. OZEMPIC® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

CONTRAINDICATIONS: OZEMPIC® is contraindicated in patients with: A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Warnings and Precautions]*; Known hypersensitivity to semaglutide or to any of the product components *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-Cell Tumors: In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC®. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated. **Pancreatitis:** In glycemic control trials, acute pancreatitis was confirmed by adjudication in 7 OZEMPIC®-treated patients (0.3 cases per 100 patient years) versus 3 in comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in an OZEMPIC®-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 OZEMPIC®-treated patients (0.27 cases per 100 patient years) and 10 placebo-treated patients (0.33 cases per 100 patient years), both on a background of standard of care. After initiation of OZEMPIC®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, OZEMPIC® should be discontinued and appropriate management initiated; if confirmed, OZEMPIC® should not be restarted. **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with OZEMPIC® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (OZEMPIC® 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (OZEMPIC® 0.7%, placebo 0.4%). Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. **Never Share an OZEMPIC® Pen Between Patients:** OZEMPIC® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. **Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin:** The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting *[see Adverse Reactions, Drug Interactions]*. **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of OZEMPIC® in patients reporting severe adverse gastrointestinal reactions. **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of OZEMPIC®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to OZEMPIC® *[see Contraindications]*. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with OZEMPIC®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with OZEMPIC®.

ADVERSE REACTIONS: The following serious adverse reactions are described below or elsewhere in the prescribing information: Risk of Thyroid C-cell Tumors *[see Warnings and Precautions]*; Pancreatitis *[see Warnings and Precautions]*; Diabetic Retinopathy Complications *[see Warnings and Precautions]*; Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin *[see Warnings and Precautions]*; Acute Kidney Injury *[see Warnings and Precautions]*; Hypersensitivity *[see Warnings and Precautions]*. **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. Pool of Placebo-Controlled Trials: The data in Table 1 are derived from 2 placebo-controlled trials (1 monotherapy trial and 1 trial in combination with basal insulin) in patients with type 2 diabetes. These data reflect exposure of 521 patients to OZEMPIC® and a mean duration of exposure to OZEMPIC® of 32.9 weeks. Across the treatment arms, the mean age of patients was 56 years, 3.4% were 75 years or older and 55% were male. In these trials 71% were White, 7% were Black or African American, and 19% were Asian; 21% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.8 years and had a mean HbA_{1c} of 8.2%. At baseline, 8.9% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 57.2%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 35.9% and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 6.9% of patients. Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients with type 2 diabetes participating in 7 placebo- and active-controlled glycemic control trials including two trials in Japanese patients evaluating the use of OZEMPIC® as monotherapy and add-on therapy to oral medications or insulin. In this pool, a total of 3150 patients with type 2 diabetes were treated with OZEMPIC® for a mean duration of 44.9 weeks. Across the treatment arms, the mean age of patients was 57 years, 3.2% were 75 years or older and 57% were male. In these trials, 60% were White, 6% were Black or African American, and 31% were Asian; 16% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.2 years and had a mean HbA_{1c} of 8.2%. At baseline, 7.8% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 63.1%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 34.3%, and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 2.5% of the patients. Common Adverse Reactions: Table 1 shows common adverse reactions, excluding hypoglycemia, associated with the use of OZEMPIC® in the pool of placebo-controlled trials. These adverse reactions occurred more commonly on OZEMPIC® than on placebo, and occurred in at least 5% of patients treated with OZEMPIC®.

Table 1. Adverse Reactions in Placebo-Controlled Trials Reported in ≥5% of OZEMPIC®-Treated Patients with Type 2 Diabetes Mellitus

Adverse Reaction	Placebo (N=262) %	OZEMPIC® 0.5 mg (N=260) %	OZEMPIC® 1 mg (N=261) %
Nausea	6.1	15.8	20.3
Vomiting	2.3	5.0	9.2
Diarrhea	1.9	8.5	8.8
Abdominal pain	4.6	7.3	5.7
Constipation	1.5	5.0	3.1

In the pool of placebo- and active-controlled trials and in the 2-year cardiovascular outcomes trial, the types and frequency of common adverse reactions, excluding hypoglycemia, were similar to those listed in Table 1. *Gastrointestinal Adverse Reactions:* In the pool of placebo-controlled trials, gastrointestinal adverse reactions occurred more frequently among patients receiving OZEMPIC® than placebo (placebo 15.3%, OZEMPIC® 0.5 mg 32.7%, OZEMPIC® 1 mg 36.4%). The majority of reports of nausea, vomiting, and/or diarrhea occurred during dose escalation. More patients receiving OZEMPIC® 0.5 mg (3.1%) and OZEMPIC® 1 mg (3.8%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.4%). In addition to the reactions in Table 1, the following gastrointestinal adverse reactions with a frequency of <5% were associated with OZEMPIC® (frequencies listed, respectively, as: placebo; 0.5 mg; 1 mg): dyspepsia (1.9%, 3.5%, 2.7%), eructation (0%, 2.7%, 1.1%), flatulence (0.8%, 0.4%, 1.5%), gastroesophageal reflux disease (0%, 1.9%, 1.5%), and gastritis (0.8%, 0.8%, 0.4%). Other Adverse Reactions: *Hypoglycemia:* Table 2 summarizes the incidence of events related to

hypoglycemia by various definitions in the placebo-controlled trials.

Table 2. Hypoglycemia Adverse Reactions in Placebo-Controlled Trials In Patients with Type 2 Diabetes Mellitus

	Placebo	OZEMPIC® 0.5 mg	OZEMPIC® 1 mg
Monotherapy			
(30 weeks)	**N=129**	**N=127**	**N=130**
Severe†	0%	0%	0%
Documented symptomatic (≤70 mg/dL glucose threshold)	0%	1.6%	3.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	1.6%	0%	0%
Add-on to Basal Insulin with or without Metformin			
(30 weeks)	**N=132**	**N=132**	**N=131**
Severe†	0%	0%	1.5%
Documented symptomatic (≤70 mg/dL glucose threshold)	15.2%	16.7%	29.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	5.3%	8.3%	10.7%

†"Severe" hypoglycemia adverse reactions are episodes requiring the assistance of another person.

Hypoglycemia was more frequent when OZEMPIC® was used in combination with a sulfonylurea *[see Warnings and Precautions]*. Severe hypoglycemia occurred in 0.8% and 1.2% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Documented symptomatic hypoglycemia occurred in 17.3% and 24.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Severe or blood glucose confirmed symptomatic hypoglycemia occurred in 6.5% and 10.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Injection Site Reactions: In placebo-controlled trials, injection site reactions (e.g., injection-site discomfort, erythema) were reported in 0.2% of OZEMPIC®-treated patients. Increases in Amylase and Lipase: In placebo-controlled trials, patients exposed to OZEMPIC® had a mean increase from baseline in amylase of 13% and lipase of 22%. These changes were not observed in placebo-treated patients. Cholelithiasis: In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients-treated with OZEMPIC® 0.5 mg and 1 mg, respectively. Cholelithiasis was not reported in placebo-treated patients. Increases in Heart Rate: In placebo-controlled trials, OZEMPIC® 0.5 mg and 1 mg resulted in a mean increase in heart rate of 2 to 3 beats per minute. There was a mean decrease in heart rate of 0.3 beats per minute in placebo-treated patients. Fatigue, Dysgeusia and Dizziness: Other adverse reactions with a frequency of >0.4% were associated with OZEMPIC® include fatigue, dysgeusia and dizziness. **Immunogenicity:** Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with OZEMPIC® may develop anti-semaglutide antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, the incidence of antibodies to semaglutide in the studies described below cannot be directly compared with the incidence of antibodies in other studies or to other products. Across the placebo- and active-controlled glycemic control trials, 32 (1.0%) OZEMPIC®-treated patients developed anti-drug antibodies (ADAs) to the active ingredient in OZEMPIC® (i.e., semaglutide). Of the 32 semaglutide-treated patients that developed semaglutide ADAs, 19 patients (0.6% of the overall population) developed antibodies cross-reacting with native GLP-1. The in vitro neutralizing activity of the antibodies is uncertain at this time.

DRUG INTERACTIONS: Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin: The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin *[see Warnings and Precautions]*. **Oral Medications:** OZEMPIC® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with OZEMPIC®.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy *(see Clinical Considerations)*. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. OZEMPIC® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In pregnant rats administered semaglutide during organogenesis, embryofetal mortality, structural abnormalities and alterations to growth occurred at maternal exposures below the maximum recommended human dose (MRHD) based on AUC. In rabbits and cynomolgus monkeys administered semaglutide during organogenesis, early pregnancy losses and structural abnormalities were observed at below the MRHD (rabbit) and ≥5-fold the MRHD (monkey). These findings coincided with a marked maternal body weight loss in both animal species *(see Data)*. The estimated background risk of major birth defects is 6–10% in women with pre-gestational diabetes with an HbA_{1c} >7 and has been reported to be as high as 20–25% in women with a HbA_{1c} >10. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. Clinical Considerations: *Disease associated maternal and fetal risk:* Poorly controlled diabetes during pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity. Data: *Animal Data:* In a combined fertility and embryofetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.1-, 0.4-, and 1.1-fold the MRHD) were administered to males for 4 weeks prior to and throughout mating and to females for 2 weeks prior to mating, and throughout organogenesis to Gestation Day 17. In parental animals, pharmacologically mediated reductions in body weight gain and food consumption were observed at all dose levels. In the offspring, reduced growth and fetuses with visceral (heart blood vessels) and skeletal (cranial bones, vertebra, ribs) abnormalities were observed at the human exposure. In an embryofetal development study in pregnant rabbits, subcutaneous doses of 0.0010, 0.0025 or 0.0075 mg/kg/day (0.03-, 0.3-, and 2.3-fold the MRHD) were administered throughout organogenesis from Gestation Day 6 to 19. Pharmacologically mediated reductions in maternal body weight gain and food consumption were observed at all dose levels. Early pregnancy losses and increased incidences of minor visceral (kidney, liver) and skeletal (sternebra) fetal abnormalities were observed at ≥0.0025 mg/kg/day, at clinically relevant exposures. In an embryofetal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (1.0-, 5.2-, and 14.9-fold the MRHD) were administered throughout organogenesis, from Gestation Day 16 to 50. Pharmacologically mediated, marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with the occurrence of sporadic abnormalities (vertebra, sternebra, ribs) at ≥0.075 mg/kg twice weekly (≥5X human exposure). In a pre- and postnatal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.7-, 3.3-, and 7.2-fold the MRHD) were administered from Gestation Day 16 to 140. Pharmacologically mediated marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with an increase in early pregnancy losses and led to delivery of slightly smaller offspring at ≥0.075 mg/kg twice weekly (≥3X human exposure). **Lactation:** Risk Summary: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats, however, due to species-specific differences in lactation physiology, the clinical relevance of these data are not clear *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OZEMPIC® and any potential adverse effects on the breastfed infant from OZEMPIC® or from the underlying maternal condition. Data: In lactating rats, semaglutide was detected in milk at levels 3-12 fold lower than in maternal plasma. **Females and Males of Reproductive Potential:** Discontinue OZEMPIC® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide *[see Use in Specific Populations]*. **Pediatric Use:** Safety and efficacy of OZEMPIC® have not been established in pediatric patients (younger than 18 years). **Geriatric Use:** In the pool of placebo- and active-controlled glycemic control trials, 744 (23.6%) OZEMPIC®-treated patients were 65 years of age and over and 102 OZEMPIC®-treated patients (3.2%) patients were 75 years of age and over. In SUSTAIN 6, the cardiovascular outcome trial, 788 (48.0%) OZEMPIC®-treated patients were 65 years of age and over and 157 OZEMPIC®-treated patients (9.6%) patients were 75 years of age and over. No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. **Renal Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in semaglutide pharmacokinetics (PK) was observed. **Hepatic Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

OVERDOSAGE: In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of OZEMPIC® of approximately 1 week.

More detailed information is available upon request.

For information about OZEMPIC® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-888-693-6742

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PATENT INFORMATION:

http://novonordisk-us.com/patients/products/product-patents.html

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From Evoke Neuroscience

The eVox® System is an FDA 510(k) cleared medical device to aid primary and specialty care physicians in diagnosis of memory loss and other cognitive disorders. eVox® measures memory loss biomarkers that may aid in detecting memory loss sooner, identifying the root cause of memory loss, and performing a differential diagnosis. eVox® procedures are performed in-office and are reimbursable by Medicare and commercial payers.

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FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

Faster test results, clinical decisions and greater practice efficiency are coming to physicians' offices with the first CLIA-waived CBC analyzer. Hematology diagnostics leader Sysmex is bringing more lab testing to the point of care. One of the most common blood tests can be conducted reliably and accurately on-site, in as few as three minutes. The device's ease of use and innovative technology means in-house staff can operate it in just a few easy steps, without lengthy certification and training. The new Sysmex XW-100 will improve health care efficiency and patient care.

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From Vitalograph

Vitalograph introduces the Compact Expert diagnostic workstation. The device is a full touch-screen based medical workstation, which comes equipped with Vitalograph's flagship Pneumotrac spirometer. This accurate, robust and linear Fleisch pneumotach produces over 50 spirometry parameters, automatically stores all test data, calibration data and clinical audit trail data in a secure network capable SQL Server database. An intuitive user interface enhances the routine workflow in most practices, allowing quick patient throughput. Beyond spirometry, it is a desktop testing station for ECG, Pulse Oximetry, Weight , COPD assessment, and Blood Pressure measurements.

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FULLY AUTOMATED QUANTITIVE IMMUNOASSAY ANALYZER

From Sekisui Diagnostics

The FastPack® IP System is a fully automated quantitative immunoassay analyzer designed for use in the Physician Office laboratory. Utilizing sophisticated chemiluminescence technology, the FastPack® IP System provides the capability to produce complex immunoassay results in 12 minutes or less with a push of a button. Menu includes Vitamin D, Testosterone, TSH, Free T4 PSA and hCG.

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of providers lose patients to other practices[1]

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1. PatientPop 2018 Online Reputation Management Survey, https://info.patientpop.com/reputation-survey-results/
https://www.patientpop.com/blog/running-a-ptactice/patient-experience/patient-retention-strategies/

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