2020 | Issue 9

Physicians office Resource™

Resources for You, Your Patients, & Your Practice

Envisioning the Delivery of True Primary Care Telehealth

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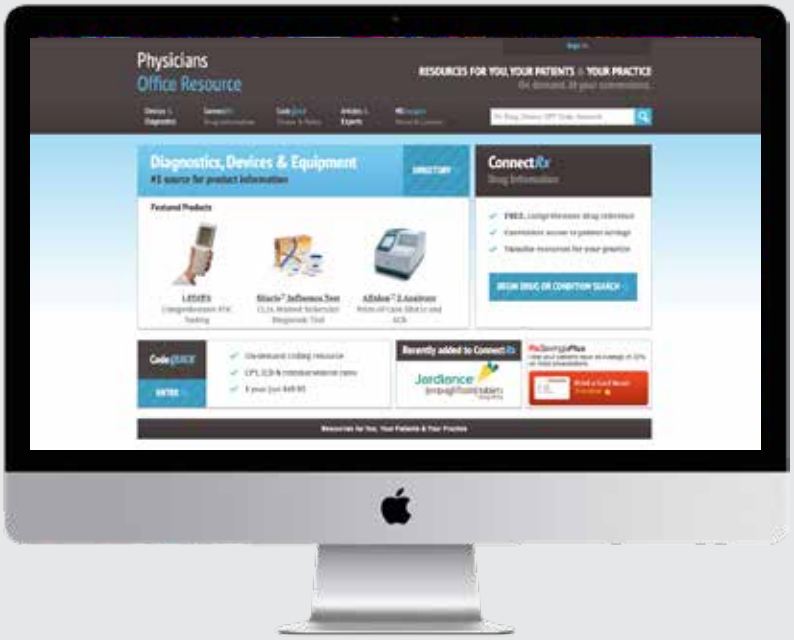


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PUBLISHER
Aaron R. Medaris
amedaris@physiciansofficeresource.com

CEO
Andrew C. Nimmo
acnimmo@physiciansofficeresource.com

PRESIDENT
John D. Pasquale
jpasquale@pharmaconnect.com

BUSINESS MANAGER
Marci J. Hills
mhills@physiciansofficeresource.com

TRAVEL EDITOR
Brandi L. Brower

EDITORIAL BOARD
Michael Paquin, FHIMSS
Barry Craig, MLT (NCA), CLC

STAFF WRITER
Dylan J. Chadwick

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Almost overnight, the COVID-19 pandemic has completely disrupted how we deliver primary care to patients. Before the pandemic, telehealth seemed to be a way to deliver urgent care for acute issues to a select group of tech-savvy patients. Now, at least in my practice, the majority of primary care (acute care, chronic disease management, and preventive care) is being delivered through "telehealth," meaning that we conduct visits virtually via video or telephone.

28 **VALUE BASED MOBILE TECHNOLOGY**

The convergence of two powerful forces are changing the practice of laboratory medicine in ways never imagined a generation ago. These twin forces are the movement to value-based healthcare from the fee-for-service model, and the rapid development of mobile technology allowing for continuous healthcare monitoring of patients beyond the clinical setting.

34 Continuous Glucose Monitoring **TURNING THE TOY IN TO A TOOL**

How many times does it happen something new comes out, you here good things about it, you take the time to learn about it so you can tell your patients about it and you actually get them to use it. However after all this this great new device which was supposed to be a tool to help the patient has turned into a toy rarely played with.



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Reference: 1. Wieman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. A phase III randomized placebo-controlled double-blind study. Diabetes Care. 1998;21:822-827.

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Envisioning the Delivery of TRUE PRIMARY CARE TELEHEALTH

BY CARA LITVIN, MD, CO-FOUNDER OF BPCORRECT (WWW.BPCORRECT.COM)



Almost overnight, the COVID-19 pandemic has completely disrupted how we deliver primary care to patients. Before the pandemic, telehealth seemed to be a way to deliver urgent care for acute issues to a select group of tech-savvy patients. Now, at least in my practice, the majority of primary care (acute care, chronic disease management, and preventive care) is being delivered through "telehealth," meaning that we conduct visits virtually via video or telephone. While, of course, this is currently safer, many patients also seem to value the improved convenience and accessibility of these visits compared to traditional office-based care. However, as we continue to move forward providing virtual care to patients during the pandemic and beyond, we need to recognize our current deficiencies in providing this type of care and acknowledge that providing the full scope of quality telehealth will require more than just a video connection with a patient. Below, I outline approaches to telehealth as framed by the chronic care model, an evidence-based approach to providing chronic disease management in the primary care setting.

CLINICAL INFORMATION SYSTEMS

The inability to collect vital signs and conduct a physical exam presents unique challenges to the delivery of telehealth. Providing true telehealth will require information systems that enable providers to remotely obtain this information when necessary. I imagine a world in the not too distant future where every home has a small telehealth kit, with a portable digital stethoscope, otoscope, thermometer, scale, pulse oximeter, and blood pressure monitor. For example, under provider guidance, a patient with ear pain could insert a home otoscope into their ear canal and securely send a picture to their doctor. Likewise, sounds transmitted by an electronic stethoscope could diagnose pneumonia or assess for arrhythmias. While home telehealth kits are currently available for niche markets, we have to ensure that affordable, accurate, and user-friendly technology is accessible to all our patients. Artificial intelligence should help providers correctly interpret the patient-generated data from these telehealth devices. We also need information systems to securely collect, store, and aggregate this information.

SELF-MANAGEMENT SUPPORT

If used correctly, telehealth has enormous potential for facilitating self-management support. For example, consider hypertension, which affects nearly half of adults in the United States. Currently, one of the most problematic issues that I encounter when providing virtual care is lack of adequate blood pressure data. The majority of patients I see do not own home blood pressure monitors, and even if they do, there is no way for me to ensure either that they have correctly obtained their blood pressure or electronically receive their readings. Providing patients with validated home blood pressure monitors, educating patients on their correct use (including both positioning and a schedule for when they should check their blood pressure), and being able to review a summary of this data via a secure portal could both better engage patients and greatly improve our ability to manage hypertension remotely.

DELIVERY SYSTEM DESIGN

We need to re-imagine our model of telehealth as much more than the interaction between a patient and her health care provider during a single video session. For example, nurses and other clinical staff members should be able to virtually review overdue lab tests or procedures with patients. They should also be able to evaluate patient-generated information that is sent to the practice, such as blood pressure readings, and notify health care providers about patients needing action. Our information systems should facilitate this team-based care by summarizing patient-generated data and highlighting actionable information. In addition, virtual group "visits" or asynchronous online support forums, facilitated by health care professionals, could supplement the traditional patient-provider interaction for chronic disease management.

DECISION SUPPORT

Providing health care virtually should not diminish our ability to use clinical decision support to guide our care. Our telehealth video platforms should seamlessly integrate with our electronic health records to ensure we have full access to the patient's chart, reminders, templates, and drug checkers at the time of the visit. We should have the capability for patients to receive and complete forms, such as the PHQ-9 depression questionnaire, during a patient visit. We should also be able to electronically share educational handouts and decision aids with patients during or after a visit.

THE HEALTH SYSTEM

It is imperative that our health systems continue to recognize telehealth as a means of providing quality, patient-centered care in the post-pandemic era. This will require continued reimbursement for telehealth services by both public and private payers, along with the evolution of billing codes to support telehealth visits, remote patient monitoring, and chronic care management. We need an accelerated shift away from payment based on encounter-based care to value-based care. We also need efficient health information exchange using open-APIs to break down our current medical information silos and allow aggregation of patient-generated data from multiple sources. Our quality metrics should capture patient-generated data if collected properly. Privacy restrictions, many of which have been waived during the pandemic, will need to be re-evaluated to ensure that patient health information remains adequately protected.

> "...as we continue to move forward providing virtual care to patients during the pandemic and beyond, we need to recognize our current deficiencies in providing this type of care..."

THE COMMUNITY

Telehealth has the potential to dramatically improve access to care. "Virtual" visits eliminate the need for patients to take time away from work, find transportation, and travel to the doctor's office. For example, through telehealth, instead of a typical visit every three months, a diabetic patient can be seen virtually every week as needed. Visits for acute care can be conducted nearly instantaneously. However, during this recent detonation of telehealth, we have quickly identified major barriers. Many patients do not have access to a smartphone or do not know how to use them for video visits. Broadband internet is limited in many rural areas. We can overcome many of these issues by expanding broadband access in rural areas, utilizing cell phone networks if possible, ensuring that software undergoes usability testing by older adults, and providing training to both patients and their caregivers.

Over the past few months, the COVID-19 pandemic has catapulted us into a new telehealth era. For many, this transition has been patch-worked together to enable us to continue to implement our previous delivery model during a crisis. As we move forward, it is imperative that we remember to apply proven evidence-based strategies for providing quality health care to telehealth, while also re-imagining how technology can help us deliver care in a world where "Zoom" is now the new norm.



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- Provides a 1 page summary report
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3 ALLERGY TESTING

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- Reimburses average $270 - $350/test, costs ~ $100/test (antigens/applicators)
- Options for Immunotherapy Treatment

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4 NEURO-COGNITIVE TESTING

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- Is woman controlled
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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi™ clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi™ in females of reproductive potential with history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or experiencing urinary tract symptoms.**
- **To discontinue Phexxi™ if they develop a local hypersensitivity reaction.**
- **That Phexxi™ does not protect against HIV infection or other sexually transmitted infections.**

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Phexxi™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

Phexxi™ is not effective for the prevention of pregnancy when administered after intercourse.

Please see full Prescribing Information for Phexxi™.

Please see Brief Summary on the following page.

REFERENCES: 1. Phexxi™ Vaginal Gel. Medi-Span®; June 8, 2020. **2.** Phexxi™ [Prescribing Information]. Evofem Biosciences, Inc: San Diego, CA; May 2020. **3.** Bayer LL, Jensen JT. ACIDFORM: a review of evidence. *Contraception*. 2014;90:11-18. **4.** Nayak S, Avery A, McLeod Griffis J, Charles CD, Culwell KR. A randomized placebo-controlled pilot study of the effect and duration of Amphora, a multipurpose vaginal pH regulator, on vaginal pH. *Clin Exp Obstet Gynecol*. 2019;46(5):736-742. **5.** Mansour D. International survey to assess women's attitudes regarding choice of daily versus nondaily female hormonal contraception. *Int J Womens Health*. 2014;6:367-375. **6.** Daniels K, et al. Current contraceptive status among women aged 15-49: United States, 2015-2017. *NCHS Data Brief*. 2018;327:1-14.

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phexxi™

(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

BRIEF SUMMARY: Consult the Package Insert for complete Prescribing Information

INDICATIONS AND USAGE

PHEXXI™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

PHEXXI is not effective for the prevention of pregnancy when administered after intercourse.

WARNINGS AND PRECAUTIONS

Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXXI in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXXI in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Clinical Trials Experience

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

The safety of PHEXXI (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXXI for 13 cycles.

Hypersensitivity Reaction:

Of the 2804 PHEXXI-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXXI use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXXI.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥ 2%) reported by subjects using PHEXXI in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXXI to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXXI (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection†,‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

*Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.

†Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.

‡Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].

Among subjects who used PHEXXI in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners:

Among male partners of subjects who used PHEXXI for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There is no use for PHEXXI in pregnancy; therefore, discontinue PHEXXI during pregnancy. There are no data with the use of PHEXXI in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of PHEXXI have been established in females of reproductive potential.

Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXXI before menarche is not indicated.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use).

Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXXI before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1) of PHEXXI Full Prescribing Information*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To discontinue PHEXXI if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To contact their health care provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].
- That PHEXXI does not protect against HIV infection and other sexually transmitted infections.

Manufactured for Evofem, Inc.,
a wholly owned subsidiary of Evofem Biosciences, Inc.,
12400 High Bluff Drive, Suite 600, San Diego, CA 92130

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U.S. Patent 6,706,276

REFDOC-000554

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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From Carolina Liquid Chemistries

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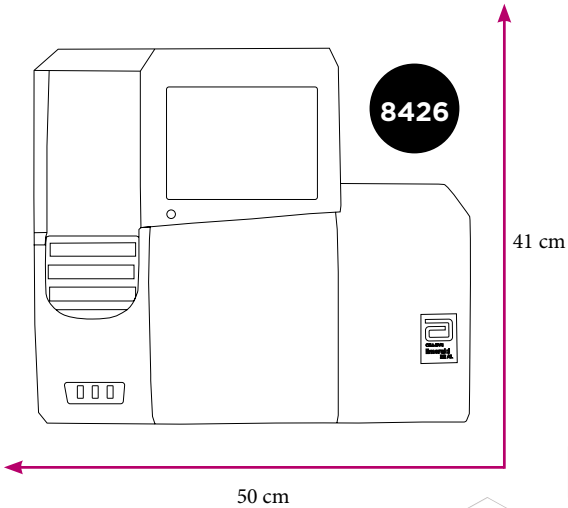
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AJOVY®
(fremanezumab-vfrm)
injection 225 mg/1.5 mL



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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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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.

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

teva

FRE-42210 February 2020



VALUE-BASED MOBILE TECHNOLOGY

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

Introduction

The convergence of two powerful forces are changing the practice of laboratory medicine in ways never imagined a generation ago. These twin forces are the movement to value-based healthcare from the fee-for-service model, and the rapid development of mobile technology allowing for continuous healthcare monitoring of patients beyond the clinical setting.

The central focus of value-based medicine is increasing the value of medical services provided for patients based on the health outcomes achieved per dollar spent. The goal is to achieve good outcomes efficiently. This is the most effective way to truly contain health care costs. Achieving and maintaining good health is inherently less costly than dealing with poor health; reminiscent of the old adage "an ounce of prevention…."

Laboratories can impact the value proposition by increasing the speed and accuracy of correct diagnoses, monitoring patient health to prevent disease, providing rapid turnaround times that allow reduction in length of hospital stays, and promoting the most appropriate test selection options with applicable interpretations in order to help avoid adverse events and point to the most appropriate treatment protocol. Translating concept into practice, however, can be challenging. Generally, the biggest hurdle is obtaining the necessary data, which must be in the right format and of sufficient quality for decision makers to gain the medical information they need.

This is why Point of Care testing (POCT) has become the fastest growing area of laboratory medicine; bringing laboratory testing conveniently and immediately to the patient. The new technology is the merger of molecular biology, information technology, and biomedical engineering. POCT increases the likelihood that the patient, physician, and care team will receive the results sooner, which allows for immediate clinical management decisions to be made. With fast turnaround times and portability to a variety of settings, POCT offers many advantages for disease management. It enables migration of testing from core hospital labs to specialty-care units, doctors' offices, retail settings, and homes to provide access to healthcare services, thus improving patient compliance, reducing hospital stays, and lowering overall healthcare costs.

It is this need for immediacy in data collection and dissemination that is further driving mobile technology past POCT to wearable devices that monitor everything from glucose levels to cardiac function. This cuts costs, as well as increases connectivity and provides the platform for shared medical data in real time.

This system allows patients to be constantly followed, alerting them and their providers when health issues are amiss. We are moving rapidly from POCT in the context of portable bedside devices run by medical personnel, to portable devices run by the patient, and now, wearable devices worn by the patient for continuous monitoring. These are fed back to healthcare providers, information is tracked on a continuous basis, allowing assessments of the effectiveness of medication and treatment.

Wearable Digital Technology: Coming to a Joint near you

This new mobile technology is based on the same mobile platforms for smart phones and tablets. It is expected that mobile technology will enable virtually universal quality, cost-effective, preventable healthcare even in lesser developed countries, in much the same way that mobile phone technology has allowed countries to leapfrog beyond land-line phones to the cell phone era and all its possibilities.

It is now clear that the technology industry sees medicine as the next frontier for exponential growth. Companies such as Apple, Google, Microsoft and Samsung and hundreds of start-ups also see the market potential — and have big plans. This is happening because several technologies such as computers,

The convergence of two powerful forces are changing the practice of laboratory medicine in ways never imagined a generation ago.

sensors, robotics and artificial intelligence are advancing at exponential rates. Their power and performance are increasing dramatically as their prices fall and their dimensions shrink.

We will soon have sensors that monitor almost every aspect of our body's functioning, inside and out. They will be packaged as wearables, as watches, adhesive bandages, clothing and contact lenses. They will be in our toothbrushes, toilets and showers. They will also be embedded in smart pills that we swallow. The data from these will be uploaded into cloud-based platforms

Artificial intelligence-based apps will constantly monitor our health data, predict disease and warn us when we are about to get sick. They will advise us on what medications we should take and how we should improve our lifestyle and habits.

All this will translate to improved patient care through patient centered preventive medicine at reduced cost, and to the more efficient treatment of both acute and chronic illnesses; the very definition of quality care.

A report by PricewaterhouseCoopers' Health Research Initiative (HRI) evaluated the benefits of wearable digital technology and devices. These include:

1. Moving diagnostic testing of basic conditions into the hands of patients: Close to 42% of physicians are comfortable relying on at-home test results to prescribe medication.

2. Increasing patient-clinician interaction: Half of physicians said that e-visits could replace more than 10% of in-office patient visits, and nearly as many consumers indicated they would communicate with caregivers online.

3. Promoting self-management of chronic disease using health apps: 28% of consumers said they have a healthcare, wellness, or medical app on their mobile device, up from 16% last year. Nearly 66% of physicians would prescribe an app to help patients manage chronic diseases such as diabetes.

4. Helping caregivers work more as a team: 79% of physicians and close to 50% of consumers believe using mobile devices can help physicians better coordinate care.

It's clear from HRI's report that major stakeholders in the healthcare industry including hospitals, insurers and the pharmaceutical industry all believe that major changes will occur in how healthcare is delivered.

However, there are several potential barriers that may inhibit or delay the implementation of this new paradigm of healthcare. These include issues of security, privacy, consumer consent, data-sharing, fragmented workflows and digital buy-in.

The Impact of Mobile Technology on the Laboratory

These trends portend a future of value-based medicine involving widespread use of remote monitoring of almost everyone, throughout their lives: preventive medicine to spot health issues before they arise (for example, based on genomic studies showing potential for disease occurrence), as well as for ongoing monitoring of chronic medical conditions.

One of the key areas of laboratory to physician communication is that of reporting critical values. Since critical values are defined as abnormal test results that are potentially life threatening and require a rapid response from caregivers, any steps taken to improve this process impacts the quality of patient care. This not only refers to the timeliness of reporting test results, but ensuring that these results reach the intended physicians no matter where they are; and that the information sent and received is secure.

Thanks to the rapid spread of mobile technology, including mobile phones, pagers, pads, and computers linked to electronic health records, new more secure messaging systems to report critical values are available. These systems offer security that normal cellphone text messaging lacks, and their two-way capabilities automate the kind of closed-loop system that patient safety experts have advocated. These mobile-friendly applications can keep critical results from falling through the cracks. They create an audit trail of message sending, delivery, and receipt, and labs can configure software that escalates an alert when the initial caregiver does not respond in a timely manner. The application of mobile technology to real-time patient monitoring using wearables synced to mobile phones, enables the immediate transmission of any detected critical values to the laboratory's electronic health records system (EHR.), and the physician notified immediately.

As wearable technology and devices proliferate, clinical laboratorians must be prepared to process the data received from these varied sources, including new types of information, such as real time patient locations and environmental factors during data collection. This data must be organized, stored and transmitted to the attending physicians and /or patients directly in as timely a manner as possible.

As a result, laboratories will not only remain centers of actual testing, but become huge data base handlers as well. Direct access to patient test results by the patients themselves opens up another huge highway of interaction with the public; another huge challenge to meet the demand for data.

Artificial intelligence-based apps will constantly monitor our health data, predict disease and warn us when we are about to get sick. They will advise us on what medications we should take and how we should improve our lifestyle and habits.

The appellation "data central" may not adequately describe the level of importance that laboratory medicine will have, where data handling may well win the competition for space with diagnostic instrumentation.

As value-based healthcare becomes the prevailing model for healthcare delivery, laboratory testing will be focused on prevention, diagnosis, and the management of chronic diseases. In this scenario, the cost of the test versus reimbursement will not be the deciding factor on whether to perform the test. Instead the focus will be on what it can save the patient and the entire organization by enabling early detection. The increased application of digital mobile technology advances this goal.

The paradigm shift in healthcare from episodic care to chronic-care management; from reactive to preventive care, represents a once-in-a-generation opportunity for proactive laboratories to redefine their value in a new, much larger role as integrators of critical clinical information and decision support.

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INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

Contraindication

ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids, or any components of the product.

Warnings and Precautions

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. Serious events have been reported with epidural and intrathecal administration of corticosteroids and none are approved for this use. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Hypersensitivity Reactions:** Rare instances of anaphylaxis, including serious cases, have occurred in patients with hypersensitivity to corticosteroids.
- **Joint Infection and Damage:** A marked increase in pain accompanied by local swelling, restriction of joint motion, fever, and malaise are suggestive of septic arthritis. Examine joint fluid to exclude a septic process. If diagnosis is confirmed, institute appropriate antimicrobial therapy. Avoid injecting corticosteroids into a previously infected or unstable joint. Intra-articular administration may result in damage to joint tissues.
- **Increased Risk of Infections:** Infection with any pathogen in any location of the body may be associated with corticosteroid use. Corticosteroids may increase the susceptibility to new infection and decrease resistance and the ability to localize infection.
- **Alterations in Endocrine Function:** Corticosteroids can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period, institute corticosteroid replacement therapy.
- **Cardiovascular and Renal Effects:** Corticosteroids can cause blood pressure elevation, salt and water retention, and increased potassium excretion. Monitor patients with congestive heart failure, hypertension, and renal insufficiency for edema, weight gain, and electrolyte imbalance. Dietary salt restriction and potassium supplementation may be needed.
- **Increased Intraocular Pressure:** Corticosteroid use may be associated with increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.
- **Gastrointestinal Perforation:** Corticosteroid administration may increase risk of gastrointestinal perforation in patients with certain GI disorders and fresh intestinal anastomoses. Avoid corticosteroids in these patients.
- **Alterations in Bone Density:** Corticosteroids decrease bone formation and increase bone resorption. Special consideration should be given to patients with or at increased risk of osteoporosis prior to treatment.
- **Behavior and Mood Disturbances:** Corticosteroids may cause adverse psychiatric reactions. Prior to treatment, special consideration should be given to patients with previous or current emotional instability or psychiatric illness. Advise patients to immediately report any behavior or mood disturbances.

Adverse Reactions

The most commonly reported adverse reactions (incidence ≥1%) in clinical studies included sinusitis, cough, and contusions.

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

July 2020. Z-01227

ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) for intra-articular use

BRIEF SUMMARY OF PRESCRIBING INFORMATION: See package insert for full Prescribing Information.

1. INDICATIONS AND USAGE

ZILRETTA is indicated as an intra-articular (IA) injection for the management of osteoarthritis (OA) pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

4. CONTRAINDICATION

ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide (TA), corticosteroids (CSs), or any components of the product.

5. WARNINGS AND PRECAUTIONS

5.1 Warnings and Precautions Specific for ZILRETTA ZILRETTA has not been evaluated and should not be administered by the following routes: epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous.

5.2 Serious Neurologic Adverse Reactions With Epidural and Intrathecal Administration Serious neurologic events, some resulting in death, have been reported with epidural injection of CSs. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. Reports of serious medical events have been associated with the intrathecal route of CS administration. The safety and effectiveness of epidural and intrathecal administration of CSs have not been established, and CSs are not approved for this use. In particular, the formulation of ZILRETTA should not be considered safe to use for epidural or intrathecal administration.

5.3 Hypersensitivity Reactions Rare instances of anaphylaxis have occurred in patients with hypersensitivity to CSs. Cases of serious anaphylaxis, including death, have been reported in individuals receiving TA injection, regardless of the route of administration. Institute appropriate care if an anaphylactic reaction occurs.

5.4 Joint Infection and Damage IA injection of a CS may be complicated by joint infection. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and a diagnosis of septic arthritis is confirmed, institute appropriate antimicrobial therapy. Avoid injection of a CS into an infected site. Local injection of a CS into a previously infected joint is not usually recommended. Examine any joint fluid present to exclude a septic process. CS injection into unstable joints is generally not recommended. IA injection may result in damage to joint tissues.

5.5 Increased Risk of Infections Intra-articularly injected CSs are systemically absorbed. Patients who are on CSs are more susceptible to infections than healthy individuals. There may be decreased resistance and inability to localize infection when CSs are used. Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the body may be associated with the use of CSs alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of CSs, the rate of occurrence of infectious complications increases. CSs may also mask some signs of current infection. Advise patients to inform their health care provider (HCP) if they develop fever or other signs or symptoms of infection. Advise patients who have not been vaccinated to avoid exposure to chicken pox or measles. Instruct patients to contact their HCP immediately if they are exposed.

5.6 Alterations in Endocrine Function CSs can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period (as in trauma, surgery, or illness), institute CS replacement therapy. Metabolic clearance of CSs is decreased in hypothyroid patients and increased in hyperthyroid patients.

5.7 Cardiovascular Effects CSs can cause elevations of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with synthetic derivatives. Monitor patients with congestive heart failure (CHF) or hypertension for signs of edema, weight gain, and imbalance in serum electrolytes. Dietary salt restriction and potassium supplementation may be necessary.

5.8 Renal Effects CSs can cause salt and water retention, and increased excretion of potassium. These effects are less likely to occur with synthetic derivatives. All CSs increase calcium excretion. Monitor patients with renal insufficiency for signs of edema, weight gain, and imbalance in serum electrolytes. Dietary salt restriction and potassium supplementation may be necessary.

5.9 Increased Intraocular Pressure CS use may be associated with development or exacerbation of increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.

5.10 Gastrointestinal (GI) Perforation CS administration is associated with increased risk of GI perforation in patients with certain GI disorders such as active or latent peptic ulcers, diverticulosis, diverticulitis, ulcerative colitis, and in patients with fresh intestinal anastomoses. Avoid CSs in these patients because signs of peritoneal irritation following GI perforation may be minimal or absent.

5.11 Alterations in Bone Density CSs decrease bone formation and increase bone resorption through their effect on calcium regulation and inhibition of osteoblast function. Special consideration should be given to patients with or at increased risk of osteoporosis (eg, postmenopausal women) before initiating CS therapy.

5.12 Behavioral and Mood Disturbances CS use may be associated with new or aggravated adverse psychiatric reactions ranging from euphoria, insomnia, mood swings, and personality changes to severe depression and frank psychotic manifestations. Special consideration should be given to patients with previous or current emotional instability or psychiatric illness before initiating CS therapy. Advise patients and/or caregivers to immediately report any new or worsening behavior or mood disturbances to their HCP.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in clinical studies of another drug and may not reflect rates observed in practice. The data below reflect exposure to a single 32mg IA injection of ZILRETTA in clinical studies in patients with moderate to severe pain due to knee OA. Clinical studies included randomized, double-blind, parallel-group, placebo- and/or active-controlled, and pharmacokinetic/pharmacodynamic studies with follow-up ranging from 6–24 weeks. 424 patients received ZILRETTA; 262 received placebo. The most commonly reported treatment-emergent adverse reactions (incidence ≥1% with ZILRETTA) in the ZILRETTA vs placebo arms were sinusitis, cough, and contusions (2% vs 1% each) and in the injected knee were joint swelling (3% vs 2%) and contusions (2% vs 1%). Overall, the incidence and nature of adverse reactions were similar to those observed with placebo.

The safety of repeat administration of ZILRETTA was evaluated in a multicenter, open-label, single-arm study in patients with OA knee pain. 179 patients received a repeat injection on or after Week 12 (median 16.6 weeks) and were followed for 52 weeks from initial injection. As assessed by adverse event rates for the periods of baseline to second dose and second dose to the comparable period after the second dose, there were higher rates of reported mild to moderate arthralgia after the second dose (16%) than after the first dose (6%). Data from this study are insufficient to fully characterize the safety of repeat administration of ZILRETTA.

6.2 Post-marketing Experience The following adverse reactions (alphabetical by body system) have been identified during post-approval use of ZILRETTA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Endocrine: Increased blood glucose (in diabetic patients). General and administration site conditions: Pain, including injection-site pain or discomfort, and leg pain. Immune system: Hypersensitivity reactions including pruritis, rash, angioedema, anaphylaxis. Infections and Infestations: Septic arthritis. Musculoskeletal: Arthralgia, joint swelling or effusion, muscle spasms. Nervous system: Headache. Reproductive system: Postmenopausal vaginal bleeding (similar to a menstrual period). Skin and Subcutaneous Tissue: Pruritis.

6.3 Corticosteroid Adverse Reactions The following adverse reactions (alphabetical by body system) are from voluntary reports or clinical studies of CSs. Because some of these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Anaphylactic reactions: Anaphylaxis including death, angioedema. Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, CHF, hypertension, fat embolism, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis. Dermatologic: Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, lupus erythematosus-like lesions, purpura, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria. Endocrine: Decreased carbohydrate and glucose tolerance, development of Cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress as in trauma, surgery, or

continued on next page

illness), suppression of growth in pediatric patients. Fluid and electrolyte disturbances: Congestive heart failure (CHF) in susceptible patients, fluid retention, sodium retention. Gastrointestinal (GI): Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis. Metabolic: Negative nitrogen balance due to protein catabolism. Musculoskeletal: Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular [IA] or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, post-injection flare (following IA use), steroid myopathy, tendon rupture, vertebral compression fractures. Neurologic/Psychiatric: Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychiatric disorders, vertigo. After intrathecal administration—arachnoiditis, meningitis, paraparesis/paraplegia, sensory disturbances. After epidural administration—spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke (including brainstem). Ophthalmic: Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections. Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

7. DRUG INTERACTIONS

No drug–drug interaction studies have been conducted with ZILRETTA® (triamcinolone acetonide extended-release injectable suspension). Drug interactions associated with systemic corticosteroids (CSs) include the following. Aminoglutethimide: Aminoglutethimide may lead to a loss of CS-induced adrenal suppression. Amphotericin B injection and potassium-depleting agents: When CSs are administered concomitantly with potassium-depleting agents (ie, amphotericin B, diuretics), observe patients closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and CHF. Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in CS clearance. Anticholinesterases: Concomitant use of anticholinesterase agents and CSs may produce severe weakness in patients with myasthenia gravis. If possible, withdraw anticholinesterase agents at least 24 hours before initiating CS therapy. Anticoagulants, oral: Co-administration of CSs and warfarin usually results in inhibition of response to warfarin, though there have been some conflicting reports. Therefore, monitor coagulation indices frequently to maintain desired anticoagulant effect. Antidiabetics: Because CSs may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required. Antitubercular drugs: Serum concentrations of isoniazid may be decreased. CYP3A4 inducers (eg, barbiturates, phenytoin, carbamazepine, and rifampin): Drugs that induce hepatic microsomal drug-metabolizing enzyme activity may enhance metabolism of CSs and require that the CS dosage be increased. CYP3A4 inhibitors (eg, ketoconazole): Ketoconazole, a strong CYP3A4 inhibitor, has been reported to decrease the metabolism of certain CSs by up to 60%, leading to an increased risk of CS side effects. Cholestyramine: Cholestyramine may increase the clearance of CSs. Cyclosporine: Increased activity of cyclosporine and CSs may occur when used concurrently. Convulsions have been reported with this concurrent use. Digitalis glycosides: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia. Estrogens, including oral contraceptives: Estrogens may decrease the hepatic metabolism of certain CSs, thereby increasing their effect. Nonsteroidal anti-inflammatory drugs (NSAIDs): Concomitant use of aspirin (or other NSAIDs) and CSs increases the risk of GI side effects. Aspirin should be used cautiously in conjunction with CSs in hypoprothrombinemia. Clearance of salicylates may be increased with concurrent use of CSs. Skin tests: CSs may suppress reactions to allergy-related skin tests. Vaccines: Patients on prolonged CS therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. CSs may also potentiate the replication of some organisms contained in live attenuated vaccines. If possible, defer routine administration of vaccines or toxoids until CS therapy is discontinued.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Risk Summary: There are no data regarding use of ZILRETTA in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Published studies on the association between CSs and fetal outcomes have reported inconsistent findings and have important methodological limitations. The majority of published literature with CS exposure during pregnancy includes oral, topical, and inhaled dosage formulations; therefore, the applicability of these findings to a single IA injection of triamcinolone acetonide (TA) is limited. In animal reproductive studies from the published literature, pregnant mice, rats, rabbits, or primates administered TA during the period of organogenesis at doses that produced exposures less than the maximum recommended human dose (MRHD) caused resorptions, decreased fetal body weight, craniofacial, and/or other abnormalities such as omphalocele. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

8.2 Lactation Risk Summary: There are no available data on presence of TA in human or animal milk, effects on the breastfed infant, or effects on milk production. However, CSs have been detected in human milk and may suppress milk production. It is not known whether IA administration of ZILRETTA could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZILRETTA and any potential adverse effects on the breastfed infant from ZILRETTA.

8.3 Females and Males of Reproductive Potential CSs may result in menstrual pattern irregularities such as deviations in timing and duration of menses and an increased or decreased loss of blood.

8.4 Pediatric Use The safety and effectiveness of ZILRETTA in pediatric patients have not been established. The adverse effects of CSs in pediatric patients are similar to those in adults. Carefully observe pediatric patients, including weight, height, linear growth, blood pressure, intraocular pressure, and clinical evaluation for the presence of infection, psychosocial disturbances, thromboembolism, peptic ulcers, cataracts, and osteoporosis. Weigh potential growth effects of treatment against clinical benefits obtained and availability of treatment alternatives.

8.5 Geriatric Use Of the total number of patients administered 32mg ZILRETTA in clinical studies (N=424), 143 patients were ≥65 years old. No overall differences in safety or effectiveness were observed between elderly and younger subjects, and other reported clinical experience with TA has not identified differences in responses between elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

13. NONCLINICAL TOXICOLOGY

13.2 Animal Toxicology and/or Pharmacology Single and repeat administrations (1 injection every 3 months for a total of 3 injections) of ZILRETTA in non-arthritic knee joints of healthy dogs have been studied at ~1.9xMRHD of 32mg (based on estimated drug concentrations within the knee joints). ZILRETTA microspheres were degraded by approximately 4- and 6-months post dosing in single and repeat dose studies, respectively. Single administration resulted in slightly increased incidence, severity (minimal to slight), and/or duration of microscopic changes (infiltration of macrophages, lymphocytes, plasma cells, and fibrosis) and decreased Safranin O staining (decreased proteoglycan content in knee cartilage) vs administration of an equivalent dose of immediate-release (IR) TA. These responses were mostly reversed after 6 to 9 months post injection. Repeat administration resulted in an increase in incidence, severity (minimal to slight), and duration of microscopic changes (infiltration of macrophages, lymphocytes, plasma cells, neutrophils; fibrosis; neovascularization; granulation tissue; and debris) and decreased Safranin O staining (decreased proteoglycan content in knee cartilage) vs the equivalent dose of IR TA. These local responses were still reversing at 6 months post the last injection. No effect on the animals according to observations related to gait/walking, pain/discomfort in injected knee, local swelling, local redness, or local tenderness were noted. The clinical relevance of these findings in the arthritic knee is unknown.

The Brief Summary is based on the ZILRETTA Prescribing Information
Part Number: 60-009-04, Version 4, 01/2020

Manufactured for Flexion Therapeutics, Inc.,
10 Mall Rd., Suite 301, Burlington, MA 01803
For more information, go to ZILRETTA.com or call 1-844-FLEXION (353-9466).

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Histofreezer® Portable Cryosurgical System offers medical professionals an easy and effective method to treat nine different types of skin lesions, including common, plantar and genital warts and other common benign skin lesions. Medical professionals in primary care, internal medicine, podiatry, ob/gyn and dermatology areas of care have either added Histofreezer® to their practice offering or replaced more invasive and less tolerated procedures with Histofreezer®.

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FEATURE

TURNING THE TOY INTO A TOOL

BY DAVID KLIFF – THE DIABETIC INVESTOR

How many times does it happen something new comes out, you here good things about it, you take the time to learn about it so you can tell your patients about it and you actually get them to use it. However after all this this great new device which was supposed to be a tool to help the patient has turned into a toy rarely played with.

Here we are again as you've likely heard very good things about continuous glucose monitors (CGM), you are taking the time to educate yourself about the various systems but the last thing you want is this fantastic piece of technology to become another toy the patient doesn't play with. As an experienced CGM user and highly engaged Type 1 patient who has been covering this technology since its invention allow us to pass along a few tips.

First the very good news you can tell your patients that the days of pricking their fingers are gone forever. No more finger sticks. Next you can also tell them no more logbooks nothing to carry around but their smartphone. CGM is not just ground breaking technology it's a technology that actually makes the patients life easier. Put simply once the sensor is inserted or attached to the patients body, a very simple and nearly pain free experience, for the 10 to 14 days the patient really doesn't do all that much.

It's also important to be prepared and prepare your patient for a few things.

Data, data and more data – Remember this is a CONTINUOUS monitor so the patient is moving from a point to point system that gathered maybe 4 data points per day to a CONTINUOUS system which gathers over 250 data points per day. In the beginning this avalanche of data can be overwhelming creating lots of Wow and Why moments. Wow as for the first time the patient will see what their levels do all day and all night long. This in turn creates lots of Why moment as Why is this happening, which creates phone calls for you. (More on this in a moment)

Medical devices can and do fail or malfunction- While we would say that the majority of CGM systems are accurate and reliable they are medical devices and as such they can and sometimes do fail or malfunction. Hey this happens and honestly there is not much you or your patient can do about it but it does help to talk about this before the patients starts using the CGM.

CGM is NOT real time information and will differ from finger stick data- although the two most popular CGM systems do not require any finger stick calibrations there


Glucose Monitor
Add Note
In Range
108
mg
dL
10m ago
300
200
100
50
6:00
9:00
11:00
12:30
13:30
16:00
19:00
90 Day Overview
20 Readings/Day
21
501
126
Low
Normal
High
Recent Events
Today
This Week
This Month
19:30
108 mg/dL
19:00
142 mg/dL
18:30
87 mg/dL
18:00
72 mg/dL
17:30
73 mg/dL

is a group of patients new to CGM who check anyway to see how their CGM system matches up with their BGM system. While it can happen it's a rare occurrence when the two systems match up exactly and there are times when they provide dramatically different readings. This obviously creates more questions for you so just be prepared for the which is right question my new system or my old system.

To be very clear here the two most popular CGM systems the Dexcom G6 and Abbott FreeStyle Libre have proven to be very accurate and very reliable.Neither system requires finger stick calibrations and neither requires a patient confirm readings before they dose insulin. While no system works perfectly 100% of the time you and your patient should feel very confident that the data being seen is accurate.

Connectivity – one of the best features of CGM is they send readings to an app on the patients smartphone which then can be shared with you, a family member, friend or care giver. This is the good news, the bad news is just as sometimes there is no cell service the app and sensor don't communicate. This of course creates lots of calls to tech support.

Reports – another great feature of these apps are all the great reports they generate. Reports which create lots of Wow and Why moments. Now before we go any further you should be seeing a pattern as that's one of the greatest things about CGM as it does create lots of Wow and Why moments. Perhaps the best way to think about the difference between CGM and BGM is BGM data is like looking at a still picture while looking at CGM data is like watching a movie, that's how dramatic the difference is.

Trend Management – In the old days before CGM diabetes management was pretty much point to point as data was only available when the patient tested. With CGM diabetes management changes to managing trends rather than managing moments. CGM data allows you to see things that were only guessed at before things like time to action or duration of action. As we noted in the first part of this series CGM data provides a comprehensive overview a complete picture of what's happening.

Social Media – whether its Facebook, Twitter or Instagram social media is now part of diabetes management and CGM technology has spawned lots of chatter (some of it white noise) on social media. Having reviewed many of the diabetes dedicated web sites and blogs we'd say for the ,most part the information posted is helpful, the same goes for the various posts on Facebook. Yes there is a fair amount of ranting however for the most part we'd say social media is a net positive. However like most things related to CGM social media does create questions so be prepared. Like almost everything else in diabetes what happens with one patient does not necessarily transform to all patients.

Alarms. Alerts – These are two of the most maddening features of CGM. In one respect these alarms and alerts can be a life saver helping the patient avoid a severe hypoglycemic event or deal with a possible hyperglycemic event. They can also be very annoying and not just to the patient but anyone who happens to be around when they go off. The good news here is this feature does NOT have to be enabled and second the patient can adjust the settings as to when these alarms and alerts happen.

Skin issues – although we have never had any issues with rashes or skin irritations it does occur with some patients. Some CGM users and we are among them use skin prep pads which provide stronger adhesive so that sensor stays attached during exercise, etc. This is one area where we have found social media to be very helpful with patients sharing information as to what and what hasn't worked for their situation.

Expectations- this is THE most important aspect transitioning a patient from BGM to CGM, managing expectations. CGM creates lots of Wows and Why's which in turn creates lots of questions. What should discussed UP FRONT is who will answer these questions. While we understand that your time is valuable and that you are not compensated to analyze and interrupt all this data most patients do not understand this. Understandably as their trusted advisor they will reach out to with questions so it's imperative they have a clear understanding of what you will and will not do.

While it is true that CGM apps can share data/reports with you or your team there are certain things these reports do not tell you. They do not collect insulin dosing data nor do they collect meal data nor do they tell you if the patient was exercising, etc. Yes there are patients who will track such things and you likely know who they are already but the majority of patients don't track these things. We mention this as lots of why questions can be more easily answered with this information.

As to which system is right for your patients that like almost everything you deal with has a lot to do with who their insurance provider is and what type of patient they are. The two most popular systems are the FreeStyle Libre from Abbott and the G6 from Dexcom. Although we have had no personal experience with the Libre the patients we have spoken with who have or are using the LIbre seem very pleased.

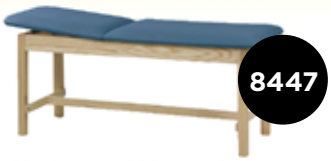
Our personal experience with the G6 has been nothing short of outstanding. The sensor is very easy to insert and yes is pretty much pain free. The sensor data has been reliable and accurate. Yes we have dealt with some connectivity issues, as have Libre users, but for the most part the G6 has matched and exceeded our expectations. We can say without question that CGM is the most transformational technology we have ever used.

We understand that adding CGM to your practice is not an easy decision which is why you need to be aware of how CGM works in the real world. However we can state unequivocally that this technology can be enlightening and transformational.

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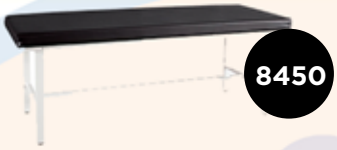
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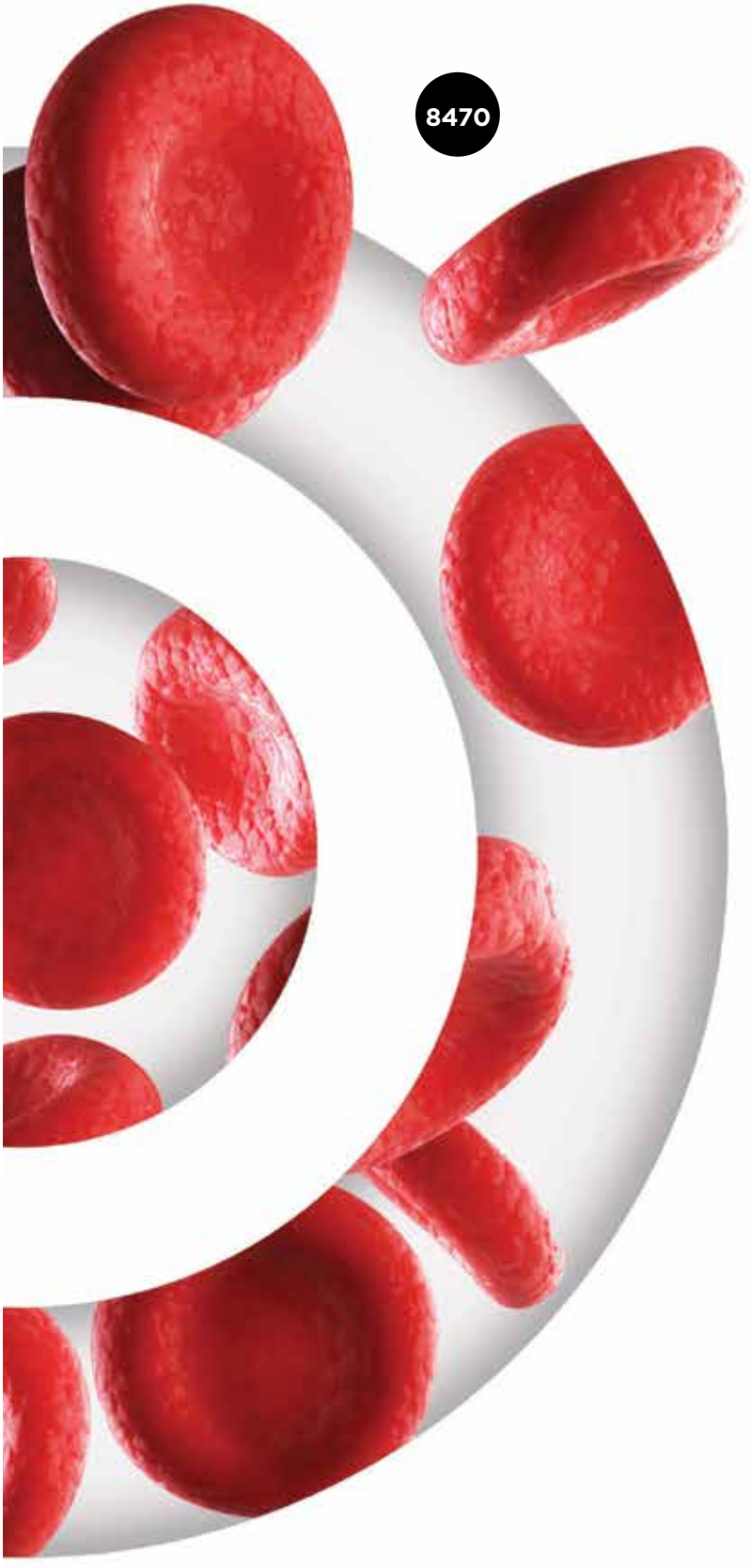
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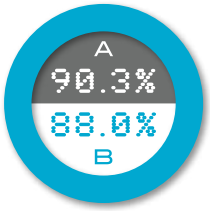


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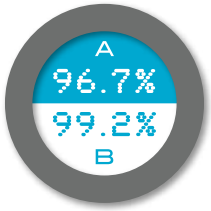
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