2020 TECHNOLOGY SURVEY RESULTS

DIGITAL DOCTORS
What’s next for the future of telehealth?
Exacerbations are frequently not reported by patients.

After one exacerbation, a patient's lung function may never recover.

Exacerbations may increase the risk of death.

References:
CHAIRMAN’S LETTER

Digital doctors are here

Telehealth has been around for decades. It took a global pandemic and economic shutdown for it to truly go mainstream with primary care physicians.

This month’s issue of Medical Economics® features our 2020 technology survey, in which we ask our physician audience to explain their technology use, including how telehealth has worked for them and what they like and don’t like about their EHRs.

The data in this year’s survey was truly eye-opening when it comes to telehealth. A whopping 93% of physicians told us they used telehealth during 2020. But what really drives that stat home is that 73% of those physicians used telehealth for the first time during the COVID-19 pandemic.

So it’s clear that telehealth’s moment has arrived. But what does the future hold for this type of patient care? Will physicians want to provide it? Will insurance companies pay for it? Will regulations snap back and make it too burdensome? Our cover story, which accompanies the data, explores all this questions.

In related technology coverage, we take a look at remote patient monitoring, and provide answers to important questions, such as: What is it? How does it complement virtual visits? How do you get paid for using it?

Medical Economics® as a brand is devoted to informing physicians of what they can do to improve their businesses and the care they provide their patients. That means exploring all the options out there, and sometimes shining a light on the difficult of traditional practice. One of the main alternatives to traditional practice is concierge medicine. But what does it take to transition a traditional practice to a concierge model? What are the benefits? What are the challenges?

In an effort to inform physicians about this practice model, we decided to highlight physicians who have made the switch in our special section this month, “Physicians of Concierge Medicine.” The 12 physicians we feature in this section — both those we interviewed and those who wrote personal essays — are great examples of physicians who took a bold step to change their lives and the lives of their patients. You can learn a great deal from their stories.

Mike Hennessy Sr.
Chairman and Founder
of MJH Life Sciences™
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DAYVIGO had no suggested physical dependence or association with rebound insomnia upon discontinuation\(^1\)

- There was no evidence of withdrawal effects upon drug discontinuation through 1 year of use, suggesting no physical dependence
- DAYVIGO contains lemborexant, a Schedule IV-controlled substance
  - Individuals with a history of abuse or addiction to alcohol or other drugs may be at an increased risk for abuse and addiction to DAYVIGO—follow such patients carefully

Get your patients started with a 5 mg dose\(^1\)

See how at DAYVIGOhcp.com

SELECTED SAFETY INFORMATION

CONTRAINDICATIONS
• DAYVIGO is contraindicated in patients with narcolepsy.

WARNINGS AND PRECAUTIONS
• Central Nervous System (CNS) Depressant Effects and Daytime Impairment:
  DAYVIGO can impair daytime wakefulness. CNS depressant effects may persist in some patients up to several days after discontinuing DAYVIGO. Prescribers should advise patients about the potential for next-day somnolence.
  Driving ability was impaired in some subjects taking DAYVIGO 10 mg. Risk of daytime impairment is increased if DAYVIGO is taken with less than a full night of sleep remaining or at a higher than recommended dose. If taken in these circumstances, patients should not drive or engage in activities requiring mental alertness.
  Use with other classes of CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of DAYVIGO and concomitant CNS depressants may be necessary when administered together. Use of DAYVIGO with other insomnia drugs is not recommended. Patients should be advised not to consume alcohol in combination with DAYVIGO.
  Because DAYVIGO can cause drowsiness, patients, particularly the elderly, are at a higher risk of falls.

Please see additional Selected Safety Information on the following page and adjacent Brief Summary of DAYVIGO full Prescribing Information.

DAYVIGO\(^8\) is a registered trademark used by Eisai Inc. under license from Eisai R&D Management Co., Ltd.
© 2020 Eisai Inc. All rights reserved. DAYV-US2766 09/2020 Distributed and marketed by Eisai Inc., Woodcliff Lake, NJ 07677
SELECTED SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONT’D)

- **Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms:** Sleep paralysis, an inability to move or speak for up to several minutes during sleep-wake transitions, hypnagogic/hypnopompic hallucinations, including vivid and disturbing perceptions can occur with DAYVIGO. Prescribers should explain these events to patients. Symptoms similar to mild cataplexy can occur with DAYVIGO and can include periods of leg weakness lasting from seconds to a few minutes, can occur either at night or during the day, and may not be associated with identified triggering event (e.g., laughter or surprise).

- **Complex Sleep Behaviors:** Complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics such as DAYVIGO. Events can occur in hypnotic-naïve and hypnotic-experienced persons. Patients usually do not remember these events. Complex sleep behaviors may occur following the first or any subsequent use of DAYVIGO, with or without the concomitant use of alcohol and other CNS depressants. Discontinue DAYVIGO immediately if a patient experiences a complex sleep behavior.

- **Patients with Compromised Respiratory Function:** The effect of DAYVIGO on respiratory function should be considered for patients with compromised respiratory function. DAYVIGO has not been studied in patients with moderate to severe obstructive sleep apnea (OSA) or chronic obstructive pulmonary disease (COPD).

- **Worsening of Depression/Suicidal Ideation:** Incidence of suicidal ideation or suicidal behavior, as assessed by questionnaire, was higher in patients receiving DAYVIGO than placebo (0.3% for DAYVIGO 10 mg, 0.4% for DAYVIGO 5 mg, and 0.2% for placebo). In primarily depressed patients treated with hypnotics, worsening of depression and suicidal thoughts and actions (including completed suicides) have been reported. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the lowest number of tablets that is feasible should be prescribed at any one time. The emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

- **Need to Evaluate for Comorbid Diagnoses:** Treatment of insomnia should be initiated only after careful evaluation of the patient. Re-evaluate for comorbid conditions if insomnia persists or worsens after 7 to 10 days of treatment. Worsening of insomnia or the emergence of new cognitive or behavioral abnormalities may be the result of an unrecognized underlying psychiatric or medical disorder and can emerge during the course of treatment with sleep-promoting drugs such as DAYVIGO.

ADVERSE REACTIONS

- The most common adverse reaction (reported in 5% of patients treated with DAYVIGO and at least twice the rate of placebo) with DAYVIGO was somnolence (10% for DAYVIGO 10 mg, 7% for DAYVIGO 5 mg, 1% for placebo).

DRUG INTERACTIONS

- **CYP3A Inhibitors:** The maximum recommended dose of DAYVIGO is 5 mg no more than once per night when co-administered with weak CYP3A inhibitors. Avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors.

- **CYP3A Inducers:** Avoid concomitant use of DAYVIGO with moderate or strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to DAYVIGO during pregnancy. Healthcare providers are encouraged to register patients in the DAYVIGO pregnancy registry by calling 1-888-274-2378. There are no available data on DAYVIGO use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on the presence of lemborexant in human milk, the effects on the breastfed infant, or the effects on milk production. Infants exposed to DAYVIGO through breastmilk should be monitored for excess sedation.

- **Geriatric Use:** Exercise caution when using doses higher than 5 mg in patients ≥65 years old.

- **Renal Impairment:** Patients with severe renal impairment may experience an increased risk of somnolence.

- **Hepatic Impairment:** The maximum recommended dose of DAYVIGO is 5 mg in patients with moderate hepatic impairment. DAYVIGO is not recommended in patients with severe hepatic impairment. Patients with mild hepatic impairment may experience an increased risk of somnolence.

DRUG ABUSE AND DEPENDENCE

- DAYVIGO is a Schedule IV-controlled substance.

- Because individuals with a history of abuse or addiction to alcohol or other drugs may be at increased risk for abuse and addiction to DAYVIGO, follow such patients carefully.

Please see adjacent Brief Summary of DAYVIGO full Prescribing Information.

Reference: 1. DAYVIGO (lemborexant) [Prescribing Information]. Woodcliff Lake, NJ: Eisai Inc.
DAYVIGO® (lemborexant) tablets, for oral use, CIV
Initial U.S. Approval: 2019
BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION 04/2020.

INDICATIONS AND USAGE
DAYVIGO is indicated for the treatment of adult patients with insomnia, characterized by difficulty with sleep onset and/or sleep maintenance.

DOSE AND ADMINISTRATION
Dosing Information
The recommended dosage of DAYVIGO 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability. Time to sleep onset may be delayed if taken with or soon after a meal.

Dosage Recommendations for Concomitant Use with CYP3A Inhibitors or CYP3A Inducers
- Co-administration with strong or moderate CYP3A inhibitors: As-administered once with weak CYP3A inhibitors: The maximum recommended dosage of DAYVIGO is no more than once per night when co-administered with weak CYP3A inhibitors. Avoid concomitant use of DAYVIGO with strong or moderate CYP3A inhibitors. Dosage Recommendation for Concomitant Use with CYP3A Inducers: The maximum recommended dose of DAYVIGO is no more than once per night in patients with moderate hepatic impairment.
Table 2: Clinically Important Drug Interactions with DAVIVIO (cont’d)

<table>
<thead>
<tr>
<th>Effect of DAVIVIO on Other Drugs</th>
<th>CPY2B6 Substrates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical impact</td>
<td>Concentrated use of DAVIVIO decreases the AUC of drugs that are CPY2B6 substrates, which may reduce efficacy for these concomitant medications, and may affect their exposure.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Patients receiving DAVIVIO are CPY2B6 substrates concomitantly should be monitored for adequate clinical response. If doses of CPY2B6 substrates may be considered as needed.</td>
</tr>
<tr>
<td>Examples</td>
<td>Depression, hypotension.</td>
</tr>
</tbody>
</table>

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to DAVIVIO during pregnancy. Healthcare providers are encouraged to report patients to the DAVIVIO pregnancy registry by calling 1-888-774-7279. Risk Summary: There are no available data on DAVIVIO use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of lemborexant to pregnant rats and rabbits during the period of organogenesis caused toxicities only at high multiples of the human exposure at the maximum recommended human dose (MRHD) based on AUC. The no-observed adverse effect levels (NOAEL) are approximately 100 and 23 times the MRHD based on AUC in rats and rabbits, respectively, similar to the administration of lemborexant to pregnant and lactating rats caused toxicities only at high multiples of the human exposure at the MRHD based on AUC. The NOAEL is 92 times the MRHD based on AUC. 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: Lemborexant was administered orally to pregnant rats during the period of organogenesis in 2 studies at doses of 80, 200, and 600 mg/kg/day or 20, 60, and 200 mg/kg/day, which are approximately 6 to 500 times the MRHD based on AUC. Lemborexant caused maternal toxicity, manifested by decreased body weight and food consumption, decreased mean fetal body weight, an increased number of dead fetuses, and skeletal, external, and visceral malformations (implacental, cleft palate, and membranous ventriculoseptal defect) at ≥50 times the MRHD based on AUC. The NOAEL of 200 mg/kg/day is approximately 143 times the MRHD based on AUC. Lemborexant was administered orally to pregnant rabbits during the period of organogenesis at doses of 10, 30, and 100 mg/kg/day which are approximately 7 to 139 times the MRHD based on AUC. Lemborexant caused maternal toxicity that consisted of decreased body weight and food consumption and a higher incidence of skeletal variations (presence of cervical rib and supernumerary lumbar vertebrae) at approximately 139 times the MRHD based on AUC. The NOAEL of 30 mg/kg/day is approximately 23 times the MRHD based on AUC. Lemborexant was administered orally to pregnant rats during pregnancy and lactation at doses of 10, 30, and 100 mg/kg/day, which are approximately 15 to 500 times the MRHD based on AUC. Lemborexant caused maternal toxicity that consisted of decreased body weight and food consumption and toxicity to offspring consisting of decreased pup body weight, decreased neonatal pup weight, and decreased pup survival at ≥50 times the MRHD based on AUC. The NOAEL of 100 mg/kg/day is approximately 97 times the MRHD based on AUC. Lactation Risk Summary: There are no data on the presence of lemborexant in human milk; the effects on the breastfed infant, or on the effects on milk production, lemborexant and its metabolites are present in the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Infants exposed to DAVIVIO through breast milk should be monitored for excessive sedation and the development and health benefits of breastfeeding should be considered along with the mother’s clinical need for DAVIVIO and any potential adverse effects on the breastfed infant from DAVIVIO or from the underlying maternal condition. Pediatric Use: The safety and effectiveness of DAVIVIO have not been established in pediatric patients. Geriatric Use: Of the total number of patients exposed to DAVIVIO (N=2,481), 49% were 65 years and over, and 67 patients were 75 years and over. Overall, efficacy results for patients ≥65 years of age were similar compared to patients ≥65 years. In a pooled analysis of Study 1 (the first 30 days), and Study 2, the incidence of somnolence in patients ≥65 years with DAVIVIO 10 mg was higher (4.8%) compared to 3.7% in patients <65 years. The incidence of somnolence with DAVIVIO 5 mg was similar in patients ≥65 years (4.9%) and ≥65 years (5.6%). The incidence of somnolence in patients treated with placebo was 2% or less regardless of age. Because DAVIVIO can increase somnolence and decrease alertness, patients, particularly the elderly, are at a higher risk of falls. Exercise caution when patients with DAVIVIO (9 mg or ≥65 years of age). Renal Impairment: No dose adjustment is required in patients with mild, moderate, or severe renal impairment. DAVIVIO exposure (AUC) was increased in patients with severe renal impairment. Patients with severe renal impairment should discontinue DAVIVIO on next-morning driving performance. Impairment may experience an increased risk of somnolence. Hepatic Impairment: DAVIVIO has not been studied in patients with severe hepatic impairment. Use in this population is not recommended. DAVIVIO exposure (AUC) in patients with moderate hepatic impairment (Child-Pugh Class B), plasma concentrations of lemborexant were increased in patients with moderate hepatic impairment (Child-Pugh Class B, DAVIVIO exposure (AUC) increased in patients with mild hepatic impairment (Child-Pugh Class A), but the terminal half-life was not changed. Patients with hepatic impairment may experience an increased risk of somnolence. Patients with Congenital Respiratory Deficiency: In a study of patients with mild U.S. (pneumonectomy index <5 episodes per hour of sleep), DAVIVIO did not increase the frequency of apneic events or cause oxygen desaturation. DAVIVIO has not been studied in patients with CPAP or moderate to severe OSA. Clinically meaningful respiratory effects of DAVIVIO in OSA or moderate to severe OSA cannot be excluded. DRUG ABUSE AND DEPENDENCE

Substance Misuse: DAVIVIO contains lemborexant, a Schedule IV controlled substance. Abuse is the intentional, non-therapeutic use of a drug, even once, for its possible physiological or psychological effects. A human abuse potential study conducted in recreational sedative abusers (N=29), lemborexant 10 mg, 20 mg (twice the maximum recommended dose), and 30 mg (three times the maximum recommended dose) produced responses on positive subjective measures such as “Drug liking,” “Overall Drug liking,” “Take Drug Again,” and “Good Drug Effects” that were statistically similar to those produced by the sedatives zolpidem (30 mg) and suxamethonium (40 mg), and statistically greater than the responses on these measures that were produced by placebo. Because individuals with a history of abuse or drug use 12 to 30 months of abstinence (measured by body sway area at 4 hours as compared to placebo). The ability to awaken in sleep in the middle of the night was assessed using an audiometer that delivered 900 Hz tones up to 12b DB. There were no meaningful differences between DAVIVIO 15 mg or 10 mg and placebo on ability to awaken to sound. A computerized performance assessment battery was administered to assess attention and memory after middle of the night awakening (4 hours postdose) in subjects receiving DAVIVIO 5 mg or 10 mg. DAVIVIO was associated with dose-dependent worsening on measures of attention and memory as compared to placebo. Patients should be cautioned about the potential for middle of the night postural instability, as well as attention and memory impairment. Effects on Next Day Postural Stability and Memory: The effects of DAVIVIO on next day postural stability and memory were evaluated in two randomized, placebo- and active-controlled trials in healthy subjects and insomnia patients aged 55 and older. There were no meaningful differences between DAVIVIO 5 mg or 10 mg and placebo on next day postural stability or memory compared to placebo. Effects on Driving: A randomized, double-blind, placebo- and active-controlled, four-hour crossover study evaluated the effects of nighttime driving on alertness, reaction time, and blood alcohol concentration (BAC) in patients with insomnia. In the crossover study, approximately 8 hours after dosing in 24 healthy elderly subjects (≥65 years, median age 67 years: 14 men, 10 women) and 24 adult subjects (median age 49 years: 12 men, 12 women), the primary driving performance measurement was change in Standard Deviation of Lateral Position (SDLP). Testing was conducted after one night [at a single dose] and after eight consecutive nights of treatment with DAVIVIO. Although DAVIVIO at doses of 5 mg and 10 mg did not cause statistically significant impairment in next-morning driving performance in adult or elderly subjects [compared with placebo], driving ability was impaired in some subjects taking 10 mg DAVIVIO. Patients using the 10 mg dose should be cautioned about the potential for next-morning driving impairment because there is individual variation in sensitivity to DAVIVIO. Rebound Insomnia: Rebound insomnia was assessed by comparing sleep diary-recorded BSI, and SAWW/P-E score. The screening period to the two-week following treatment discontinuation in both Studies 1 and 2. Analyses of group means and the proportion of patients with rebound insomnia suggest that DAVIVIO was not associated with rebound insomnia following treatment discontinuation, Withdrawal Effects: In 12-month and 1-month continuation studies and efficacy trials in adults and elderly, withdrawal symptoms were assessed by the Tyber Benedetti group3 Withdrawal Symptoms Questionnaire following discontinuation from study drug in patients who received DAVIVIO 5 mg or 10 mg. There was no evidence of withdrawal effects following DAVIVIO discontinuation at either dose. DAVIVIO® is a registered trademark of Eisai R&D Management Co., Ltd. and is licensed to Eisai Inc. ©2010-2011 Eisai Inc. All rights reserved. DAVU-04173 10/7010
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Three things you should know about this condition.
**FASENRA** is indicated as an add-on maintenance treatment of patients 12 years and older with severe eosinophilic asthma. **FASENRA** is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

What could reducing exacerbations mean for your severe asthma patients?

**TEST** for elevated blood eosinophils (≥150 cells/μL)*1,2 with a simple blood test (CBC with differential).3,4

**TARGET** eosinophils directly with **FASENRA**, a biologic that provides near complete depletion of eosinophils in 24 hours.†5-7 The mechanism of action and the relationship between the pharmacological properties and clinical efficacy has not been established.

**TREAT** with **FASENRA** for the POWER TO HELP PREVENT EXACERBATIONS and reduce oral corticosteroid use.5,8-10

HELP YOUR PATIENTS TAKE CONTROL OF THEIR ASTHMA

SCAN HERE TO LEARN MORE & SEE IF **FASENRA** IS APPROPRIATE FOR YOUR PATIENT

www.FASENRAOPTIONS.com

*Although not defined by clinical guidelines, one characterization of eosinophilic asthma can be a blood eosinophil count of ≥150 cells/μL.†1,2
†The pharmacodynamic response (blood eosinophil depletion) following repeat subcutaneous (SC) dosing was evaluated in asthma patients in a 12-week phase 2 trial. Patients received 1 of 3 doses of benralizumab [25 mg (n=6), 100 mg (n=6) or 200 mg (n=6) SC] or placebo (n=6) every 4 weeks for a total of 3 doses. Twenty-four hours post dosing, all benralizumab dosage groups demonstrated complete or near complete depletion of median blood eosinophil levels, which was maintained throughout the dosing period.†5-7

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**
Known hypersensitivity to benralizumab or excipients.

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions**
Hypersensitivity reactions (eg, anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (ie, days). Discontinue in the event of a hypersensitivity reaction. Please see additional Important Safety Information on next page and Brief Summary of full Prescribing Information on adjacent pages.
IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Acute Asthma Symptoms or Deteriorating Disease
FASENRA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Reduction of Corticosteroid Dosage
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helmint treatment, discontinue FASENRA until infection resolves.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥ 5%) include headache and pharyngitis. Injection site reactions (eg, pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo.

USE IN SPECIFIC POPULATIONS
A pregnancy exposure registry monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/fasenra.

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

INDICATION
FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

- FASENRA is not indicated for treatment of other eosinophilic conditions
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus

PLEASE SEE BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION ON ADJACENT PAGE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

STUDY DESIGNS

SIROCCO AND CALIMA (Trials 1 and 2)
SIROCCO (48-week) and CALIMA (56-week) were 2 randomized, double-blind, parallel-group, placebo-controlled, multicenter studies comparing FASENRA 30 mg SC Q4W for the first 3 doses, then Q8W thereafter; benralizumab 30 mg SC Q4W, and placebo SC. A total of 1204 (SIROCCO) and 1306 (CALIMA) patients aged 12–75 years old with severe asthma uncontrolled on high-dose ICS (SIROCCO) and medium- to high-dose ICS (CALIMA) plus LABA with or without additional controllers were included. Patients had a history of ≥2 exacerbations requiring systemic corticosteroids or hospitalization in the previous year. Patients were stratified by geography, age, and blood eosinophil counts (≥300 cells/μL and <300 cells/μL). The primary endpoint was annual exacerbation rate ratio vs placebo in patients with blood eosinophil counts of ≥300 cells/μL on high-dose ICS and LABA. Exacerbations were defined as a worsening of asthma that led to use of systemic corticosteroids for ≥3 days, temporary increase in a stable OCS background dose for ≥3 days, emergency/urgent care visit because of asthma that needed systemic corticosteroids, or inpatient hospital stay of ≥24 hours because of asthma. Key secondary endpoints were pre-bronchodilator FEV1, and total asthma symptom score at Week 48 (SIROCCO) and Week 56 (CALIMA) in the same population.

ZONDA (Trial 3)
A 28-week, randomized, double-blind, parallel-group, placebo-controlled, multicenter OCS reduction study comparing the efficacy and safety of FASENRA (30 mg SC Q4W for the first 3 doses, then Q8W thereafter; benralizumab (30 mg SC) Q4W, and placebo (SC) Q4W. A total of 220 adult (18-75 years old) patients with severe asthma on high-dose ICS plus LABA and daily OCS (7.5 to 40 mg/day), blood eosinophil counts of ≥150 cells/μL, and a history of ≥1 exacerbation in the previous year were included. The primary endpoint was the median percent reduction from baseline in the final daily OCS dose while maintaining asthma control.

REFERENCES
**FASENRA® (benralizumab) injection, for subcutaneous use**

**Initial U.S. Approval: 2017**

**Brief Summary of Prescribing Information.** For complete prescribing information consult official package insert.

**INDICATIONS AND USAGE**

FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype [see Clinical Studies (14) in the full Prescribing Information].

Limitations of use:
- FASENRA is not indicated for treatment of other eosinophilic conditions.
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus.

**DOSEAGE AND ADMINISTRATION**

**Recommended Dose**

FASENRA is for subcutaneous use only.

The recommended dose of FASENRA is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

**General Administration Instructions**

FASENRA is intended for use under the guidance of a healthcare provider. In line with clinical practice, monitoring of patients after administration of biologic agents is recommended [see Warnings and Precautions (5.1) in the full Prescribing Information].

Administer FASENRA into the thigh or abdomen. The upper arm can also be used if a healthcare provider or caregiver administers the injection. Prior to administration, warm FASENRA by leaving carton at room temperature for about 30 minutes. Visually inspect FASENRA for particulate matter and discoloration prior to administration. FASENRA is clear to opalescent, colorless to slightly yellow, and may contain a few translucent or white to off-white particles. Do not use FASENRA if the liquid is cloudy, discolored, or if it contains large particles or foreign particulate matter.

**Prefilled Syringe**

The prefilled syringe is for administration by a healthcare provider.

**Autoinjector (FASENRA PEN™)**

FASENRA PEN is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate.

**Instructions for Administration of FASENRA Prefilled Syringe (Healthcare Providers)**

Refer to Figure 1 to identify the prefilled syringe components for use in the administration steps.

![Syringe Diagram](Image)

**Do not touch the needle guard activation clips** to prevent premature activation of the needle safety guard.

1. Grasp the syringe body, not the plunger, to remove prefilled syringe from the tray. Check the expiration date on the syringe. The syringe may contain small air bubbles; this is normal. Do not expect the air bubbles prior to administration.

2. Do not remove needle cover until ready to inject. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover or the plunger may move. If the prefilled syringe is damaged or contaminated (for example, dropped without needle cover in place), discard and use a new prefilled syringe.

3. Gently pinch the skin and insert the needle at the recommended injection site (i.e., upper arm, thigh, or abdomen).

![Injecting Diagram](Image)

Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.

After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the prefilled syringe.

6. Discard the used syringe into a sharp container.

**Instructions for Administration of FASENRA PEN**

Refer to the FASENRA PEN ‘Instructions for Use’ for more detailed instructions on the preparation and administration of FASENRA PEN [See Instructions for Use in the full Prescribing Information]. A patient may self-inject or the patient caregiver may administer FASENRA PEN subcutaneously after the healthcare provider determines it is appropriate.

**CONTRAINDICATIONS**

FASENRA is contraindicated in patients who have known hypersensitivity to benralizumab or any of its excipients [see Warnings and Precautions (5.1) in the full Prescribing Information].

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions**

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred following administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, FASENRA should be discontinued [see Contraindications (4) in the full Prescribing Information].

**Acute Asthma Symptoms or Deteriorating Disease**

FASENRA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use FASENRA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA.

**Reduction of Corticosteroid Dosage**

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

**Parasitic (Helminth) Infection**

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving treatment with FASENRA and do not respond to anti-helminth treatment, discontinue treatment with FASENRA until infection resolves.

**ADVERSE REACTIONS**

The following adverse reactions are described in greater detail in other sections:
- **Hypersensitivity Reactions** [see Warnings and Precautions (5.1) in the full Prescribing Information]

**Clinical Trials Experience**

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

Across Trials 1, 2, and 3, 1,808 patients received at least 1 dose of FASENRA [see Clinical Studies (14) in the full Prescribing Information]. The data described below reflect exposure to FASENRA in 1,663 patients, including 1,556 exposed for at least 24 weeks and 1,387 exposed for at least 48 weeks. The safety exposure for FASENRA is derived from two Phase 3 placebo-controlled studies (Trials 1 and 2) from 48 weeks duration [FASENRA every 4 weeks (n=841), FASENRA every 4 weeks for 3 doses, then every 8 weeks (n=822), and placebo (n=847)]. While a dosing regimen of FASENRA every 4 weeks was included in clinical trials, FASENRA administered every 4 weeks for 3 doses, then every 8 weeks thereafter is the recommended dose [see Dosage and Administration (2.1) in the full Prescribing Information]. The population studied was 12 to 75 years of age, of which 64% were female and 79% were white. Adverse reactions that occurred at greater than or equal to 3% incidence are shown in Table 1. Table 1. Adverse Reactions with FASENRA with Greater than or Equal to 3% Incidence in Patients with Asthma (Trials 1 and 2)

<table>
<thead>
<tr>
<th><strong>Adverse Reactions</strong></th>
<th><strong>FASENRA (N=822)</strong></th>
<th><strong>Placebo (N=847)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Hypersensitivity reactions(^1)</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

1 Hypersensitivity Reactions were defined by the following terms: ‘urticaria’, ‘urticaria popular’, and ‘rash’ [see Warnings and Precautions (5.1) in the full Prescribing Information].
FASENA® (benralizumab) injection, for subcutaneous use

26-Week Trial
Adverse reactions from Trial 3 with 28 weeks of treatment with FASENRA (n=73) or placebo (n=75) in which the incidence was more common in FASENRA than placebo include headache (8.2% compared to 5.3%, respectively) and pyrexia (2.7% compared to 1.3%, respectively) [see Clinical Studies (14) in the full Prescribing Information]. The frequencies for the remaining adverse reactions with FASENRA were similar to placebo.

Injection site reactions
In Trials 1 and 2, injection site reactions (e.g., pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo.

Immunogenicity
As with all therapeutic proteins, there is 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 benralizumab in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Overall, treatment-emergent anti-drug antibody response developed in 13% of patients treated with FASENRA at the recommended dosing regimen during the 48 to 56 week treatment period. At 12% of patients treated with FASENRA developed neutralizing antibodies. Anti-benralizumab antibodies were associated with increased clearance of benralizumab and increased blood eosinophil levels in patients with high anti-drug antibody titers compared to antibody negative patients. No evidence of an association of anti-drug antibodies with efficacy or safety was observed.

The data reflect the percentage of patients whose test results were positive for antibodies to benralizumab in specific assays.

Postmarketing Experience
In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during post approval use of FASENRA. 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. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to FASENRA or a combination of these factors.

Immune System Disorders: Hypersensitivity reactions, including anaphylaxis.

DRUG INTERACTIONS
No formal drug interaction studies have been conducted.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. Healthcare providers can enroll patients or encourage patients to enroll themselves by calling 1-877-311-8972 or visiting motherho..org/Fasenra.

Risk Summary
The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of benralizumab throughout pregnancy at doses that produced exposures up to approximately 310 times the exposure at the maximum recommended human dose (MRHD) of 30 mg SC [see Data].

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

Clinical Considerations
Disease-associated maternal and/or embryo/fetal risk:
In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of pre eclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data
Animal Data
In a prenatal and postnatal development study, pregnant cynomolgus monkeys received benralizumab from beginning on GD20 to GD22 (dependent on pregnancy determination), on GD17 and 24, and 14 days thereafter throughout the gestation period and 1 month postpartum (maximum 14 doses) at doses that produced exposures up to approximately 310 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 30 mg/kg once every 2 weeks). Benralizumab did not elicit adverse effects on fetal or neonatal development (including immunophenotyping) up to 6.5 months after birth. There was no evidence of treatment-related external, visceral, or skeletal malformations. Benralizumab was not teratogenic in cynomolgus monkeys. Benralizumab crossed the placenta in cynomolgus monkeys. Benralizumab concentrations were approximately equal in mothers and infants on day 7, but were lower in infants at later time points. Eosinophil counts were suppressed in infant monkeys with gradual recovery by 6 months postpartum; however, recovery of eosinophil counts was not observed for one infant monkey during this period.

Lactation
Risk Summary
There is no information regarding the presence of benralizumab in human or animal milk, and the effects of benralizumab on the breast fed infant and on milk production are not known. However, benralizumab is a humanized monoclonal antibody (IgG1κ-class), and immunoglobulin G (IgG) is present in human milk in small amounts. If benralizumab is transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to benralizumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for benralizumab and any potential adverse effects on the breast-fed child from benralizumab or from the underlying maternal condition.

Pediatric Use
There were 108 adolescents aged 12 to 17 with asthma enrolled in the Phase 3 exacerbation trials (Trial 1: n=53, Trial 2: n=55). Of these, 46 received placebo, 40 received FASENRA every 4 weeks for 3 doses, followed by every 8 weeks thereafter, and 22 received FASENRA every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months and reduced lung function at baseline (FEV₁<90%) despite regular treatment with medium or high dose ICS and LABA with or without OCS or other controller therapy. The pharmacokinetics of benralizumab in adolescents 12 to 17 years of age were consistent with adults based on population pharmacokinetic analysis and the reduction in blood eosinophil counts was similar to that observed in adults following the same FASENRA treatment. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies [see Adverse Reactions (6.1) in the full Prescribing Information]. The safety and efficacy in patients younger than 12 years of age has not been established.

Geriatric Use
Of the total number of patients in clinical trials of benralizumab, 13% (n=323) were 65 and over, while 0.4% (n=7) were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE
Doses up to 200 mg were administered subcutaneously in clinical trials to patients with eosinophilic disease without evidence of dose-related toxicities. There is no specific treatment for an overdose of benralizumab. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

PATIENT COUNSELING INFORMATION
Advise the patients and/or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use for FASENRA PEN) before the patient starts using FASENRA and each time the prescription is renewed as there may be new information they need to know.

Provide proper training to patients and/or caregivers on proper subcutaneous injection technique using the FASENRA PEN, including aspic technique, and the preparation and administration of FASENRA PEN prior to use. Advise patients to follow sharp disposal recommendations [see Instructions for Use in the full Prescribing Information].

Hypersensitivity Reactions
Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occurred within hours of FASENRA administration, but in some instances had a delayed onset (i.e., days). Instruct patients to contact their healthcare provider if they experience symptoms of hypersensitivity reaction [see Warnings and Precautions (5.2) in the full Prescribing Information].

Not for Acute Symptoms or Deteriorating Disease
Inform patients that FASENRA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA [see Warnings and Precautions (5.2) in the full Prescribing Information].

Reduction of Corticosteroid Dose
Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Instruct patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy [see Warnings and Precautions (5.3) in the full Prescribing Information].

Exposure Registry
Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy and that they can enroll in the Pregnancy Exposure Registry by calling 1-877-311-8972 or by visiting motherho..org/Fasenra [see Use in Specific Populations (8.1) in the full Prescribing Information].

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Rev. 10/19 US-300659 10/19
COVID-19 COVERAGE CENTRAL

Medical Economics® editors are covering what you need to know during the ongoing novel coronavirus (COVID-19) pandemic. Our ongoing coverage of COVID-19 includes:

- Breaking news on the latest developments.
- Tips for physicians to extend the life of N95 respirators.
- Mental health tips for doctors and other providers.
- How physicians can protect themselves from COVID-19.
- Strategies for using telehealth.

To read all of our ongoing coverage, go to MedicalEconomics.com

Perfect your telehealth program

Tabassum Salam, M.D., the ACP’s vice president of medical education, discusses what physicians need to know to get started with telehealth right away.

Watch this video and others at: bit.ly/MedEcVideo

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Have a question for our advisers?
medec@mmhgroup.com
You’ve controlled their A1c and blood pressure. But your patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) are still at risk.¹⁻³

**INFLAMMATION AND FIBROSIS ARE DESTROYING YOUR PATIENTS’ KIDNEYS⁴**

CKD PROGRESSION IN T2D IS INFLUENCED BY 3 MAJOR DRIVERS¹⁻⁴:

**METABOLIC DRIVERS**
- Elevated blood glucose (A1c) levels

**HEMODYNAMIC DRIVERS**
- Rise in blood pressure
- High intraglomerular pressure

**INFLAMMATORY AND FIBROTIC DRIVERS⁵⁻⁶**
- Proinflammatory cytokines
- Fibrotic proteins

Today, the treatment of CKD in T2D does not adequately address inflammation and fibrosis, a major driver of CKD progression¹

IT'S TIME TO EXPLORE AN UNADDRESSED DRIVER OF CKD IN T2D AT [CKD-T2D.COM](https://www.ckd-t2d.com)

The future of telehealth for physicians

2020 TELEHEALTH & EHR SURVEY

Physicians consider a momentous year for Health IT

by Medical Economics® Staff

Have you used telehealth to see patients this year?

93% YES

7% NO
Who provides your telehealth technology?

<table>
<thead>
<tr>
<th>Provider</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free software (skype, facetime, etc.)</td>
<td>28%</td>
</tr>
<tr>
<td>Contracted third party vendor</td>
<td>24%</td>
</tr>
<tr>
<td>EHR vendor</td>
<td>12%</td>
</tr>
<tr>
<td>Hospital system</td>
<td>9%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>9%</td>
</tr>
</tbody>
</table>

Is your telehealth program integrated with your EHR?

- No: 60%
- Yes: 40%

Did the COVID-19 pandemic cause you to use telehealth for the first time?

- No: 23%
- Yes: 77%

What percentage of your patient visits were via telehealth before COVID-19?

- None: 70%
- Up to 25%: 23%
- 26% to 50%: 4%
- 51% to 75%: 1%
- 76% to 100%: 2%

What percentage of your patient visits are via telehealth now?

- None: 6%
- Up to 25%: 51%
- 26% to 50%: 17%
- 51% to 75%: 11%
- 76% to 100%: 15%

Once the COVID-19 crisis is over, what do you expect will happen with the frequency of your telehealth visits?

- Telehealth visits will decrease: 43%
- Telehealth visits will remain about the same: 26%
- Telehealth visits will increase: 13%
- I’ll stop doing telehealth visits: 10%
- Not sure: 8%
TECHNOLOGY / TELEHEALTH & EHR SURVEY

**Telehealth satisfaction**

- Not at all satisfied: 0
- Extremely satisfied: 10
- How satisfied are you with the quality of care you are able to provide your patients using telehealth? 6.8
- How satisfied are you with the telehealth TECHNOLOGY and how well it functions? 6
- How satisfied would you say your patients are with a telehealth visit? 5.9

**What are the biggest challenges you’ve faced using telehealth?**

- Explaining to patients how to use telehealth: 60%
- Internet connection/bandwidth issues: 53%
- Problems with scheduling/staff efficiency: 33%
- Patient getting distracted while on call: 25%
- Figuring out the interface: 22%
- Integrating it with existing software: 22%
- Upgrading technology so telehealth can be used: 19%
- Training office staff: 17%
- Cost: 13%

**Do you use a pre-screening process to determine whether a patient can be seen virtually or requires an office visit?**

- Yes: 36%
- No: 64%

**Have you been getting reimbursed at the same rates for virtual visits as you have for in-office visits since the beginning of the COVID-19 pandemic?**

- Yes: 44%
- No: 23%
- Don’t know: 33%

**Do you think the investment in telehealth is worth it?**

- Yes: 75%
- No: 25%
- Don’t know: 0
How long have you been using your current EHR?

![Graph showing the distribution of EHR usage lengths]

Are you or your practice considering switching to a different EHR system within the next 12 months?

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>11%</td>
</tr>
<tr>
<td>No</td>
<td>71%</td>
</tr>
<tr>
<td>Not sure</td>
<td>18%</td>
</tr>
</tbody>
</table>

What are the main reasons you or your practice switched EHRs in the past?

- EHR wasn’t user-friendly: 17%
- I wanted a product that linked to other PM systems: 16%
- I changed practice/employment: 14%
- I wanted better customization of system: 14%
- The system lacked of customer support: 13%
- I found a more affordable system: 9%
- My old system wasn’t certified for meaningful use/MACRA: 7%
- My vendor went out of business: 5%
- I haven’t switched: 48%

What capabilities are you or your practice looking for in a new EHR system that your current system lacks?

- One that’s easier to use: 38%
- An improved ability to customize: 33%
- An improved quality metrics measuring (e.g., MACRA): 25%
- Better population health capability: 24%
- Better vendor support: 23%
- Less expensive: 23%
- Better billing capabilities: 20%
- I want a cloud-based system: 17%
- I am not switching EHRs: 46%
How much does your practice spend annually to maintain its current EHR?

- less than $5,000: 16%
- $5,000 to $9,999: 8%
- $10,000 to $19,999: 12%
- $20,000 to $49,999: 10%
- $50,000 or more: 12%
- I haven’t had current EHR for an entire year: 3%
- I don’t know: 40%

Telehealth ratings

- Interoperability: 4.7
  Ease of sharing records with the other providers/hospitals, of importing data into your EHR and sharing data with patients, etc.

- Implementation & Training: 5.7
  The quality and amount of training your practice received and ease of customization or configuration to meet your practices’ needs, etc.

- Customer Service: 5.7
  The vendor’s ability to resolve technical problems, their response time, average wait time on a support call, etc.

- Productivity: 6
  Ease of use, of moving from one section of your EHR to another, navigating during a patient visit, frequency of useful pop-ups and alert, etc.

What best describes the type of practice where you work?

- independent: 66%
- owned by a hospital/health system: 23%
- academic: 4%
- part of a government system: 1%
- Federally Qualified Health Center: 1%

What best describes your practice’s specialty?

- general internal medicine (IM): 21%
- pediatrics: 12%
- OB/GYN: 5%
- IM specialty (please specify): 5%
- cardiology: 3%
- psychiatry: 3%
- multispecialty: 3%
- dermatology: 2%
- emergency medicine: 2%
- surgery: 2%
- urology: 1%

Overall Score: 5.5
While physicians are a source of strength in our communities, ISMIE is here to help sustain that strength.

Our Wellness Center – ismie.com/wellness – is continually evolving to better meet the needs of our policyholders, helping you navigate personal and professional challenges.

For answers to your COVID-19-specific questions, please visit ismie.com/COVID-19.
When the COVID-19 pandemic started to sweep through the United States, primary care physicians saw the number of office visits either dramatically drop or cease all together. Between lockdowns that encouraged people to stay home and fearful patients who didn’t want to risk potentially exposing themselves to the virus, many doctors saw their livelihoods threatened as appointment cancellations piled up.

As a result, the Centers for Medicare & Medicaid Services changed Medicare payment policies to reimburse telehealth visits for a wider range of care, and some Health Insurance Portability and Accountability Act (HIPAA) restrictions were temporarily loosened to make it easier for doctors to communicate with their patients through whatever devices they chose. Prior to the pandemic, telehealth would only be reimbursed by Medicare for limited circumstances, such as patients living in rural areas with little access to care. The communication changes removed requirements for patients to only use often clunky HIPAA-compliant platforms, opening up the ability to use smartphones and increasing consumer convenience. Most private payers also followed Medicare’s lead and changed their reimbursement policies.

“The fear from patients and the change in payment policies really drove and facilitated an incredibly high spike in demand for telehealth,” said Anders Gilberg, senior vice president, government affairs, for Medical Group Management Association.

Practices with telehealth capabilities quickly ramped up their capacity, while others installed the technology needed to conduct remote visits. According to the Medical Economics® 2020 Telehealth-EHR survey, more than 77% of doctors surveyed used telehealth for the first time because of COVID-19.

“It was a lifeline for medical practices,” Gilberg said. Patients and doctors alike embraced the technology and the convenience, and practices began to collect income again.

Gabe Charbonneau, M.D., a family physician in Stevensville, Montana, saw the number of in-office visits plummet early in the pandemic. “We really quickly ramped up doing telemedicine, and about half of our visits were on Zoom,” he said. “Because it was such a financial hit, there was a lot of pressure for us to figure out how to get people back in for visits.”

The pandemic quickly proved that telehealth could be a lifeline for practices.

“If there’s a silver lining to this pandemic, it’s the advances made in telehealth,” said Thomas Ely, D.O., president of the American Osteopathic Association.

But as the intensity of the pandemic wanes and people are becoming more comfortable returning for office visits, the future of telehealth is in question. “We had practices at one point that were almost doing 100% telehealth visits, but that has come down considerably, even though the payment policies from Medicare are still in place,” Gilberg said.

Charbonneau saw his practice’s telehealth visits drop as patients shifted back to in-office visits. “Some days, we might have two or three telehealth visits, if that,” he said.

When the public health emergency ends, so will the changes that have made telehealth viable, Gilberg says. “In order to make telehealth permanent, it needs to have a viable reimbursement structure behind it, and it’s only going to
be permanent if Congress steps in at the federal level.”

While there is interest from both Democrats and Republicans in making such changes, there are unanswered questions about telehealth in the long term.

Is Congress really committed to telehealth?

Despite telehealth being a great solution to some challenges the pandemic created early on, there are still questions that Congress will want answered before making any permanent changes to reimbursement for telehealth.

“I think Congress may not necessarily be looking at full, permanent telehealth coverage, but perhaps an effort to cover it beyond the public health emergency, and then [Congress can] study what its impact is on utilization, cost and quality,” Gilberg said. “It still remains to be seen whether you can provide the same quality of service without a hands-on approach with the patient.”

In some areas, such as behavioral health, where a physical examination may not be needed and a patient might be more comfortable not being in a doctor’s office, it might be an easier sell to Congress to allow for more telehealth. The same goes for chronic care management, where a simple check-in may be all that’s required.

But will telehealth still have the same appeal if it’s more difficult to use once the public health emergency is over?

“It’s likely to be limited to HIPAA-compliant platforms, so no more just dialing up your physician on FaceTime or Zoom or something like that,” Gilberg said. “Consumers today, they demand a certain degree of convenience, so there’s that aspect. Then there’s also, especially among the Medicare population, I think they trust that when they go to the doctor they prefer a hands-on examination,” he said.

Congressional leaders, who have already expressed concerns about rising health care costs, also have to wrestle with the idea that a more convenient telehealth service might be unaffordable.

“One of the reasons that telehealth expansion in Medicare hasn’t really become a reality yet is because there has been a concern that if you have broad coverage, that it would increase volume and potentially increase unnecessary care, because it’s just too convenient,” Gilberg said.

“The Congressional Budget Office believes it would increase Medicare volume on the physician side and therefore potentially drive up costs of the program to the government. The other side of that is, if you can do some of the preventive things more conveniently and keep patients out of the hospital, that will, in the long run, save money from expensive in-patient types of utilization.”

Even if Congress makes telehealth policy changes permanent, reimbursement rates would likely be lower for virtual visits than they are now. “CMS determined that physicians would largely [have lower] overhead costs and fewer practice expenses when they utilize telehealth, even though I don’t think most medical practices would agree with that,” said Gilberg, who added that the reimplementation of all HIPAA requirements would necessitate using a compliant platform, which entails vendor costs to the practice. “And prior to the pandemic, telehealth visits were reimbursed less than in-person visits, at least in Medicare.”

What private payers think about telehealth

Most private payers tend to follow whatever Medicare does when it comes to reimbursement, so when Medicare boosted telehealth, most of them did the same. While private insurers remain interested in telehealth, it may not be a boon for private practices, even if they decide to continue reimbursement after the public health emergency ends.

“There are different types of deals and relationships, not necessarily among physician practices and health plans, but instead, they are associating themselves with telehealth vendor platforms that they might have a financial interest in,” Gilberg said. “If you’re a patient, you would call in and maybe
get a doctor or maybe talk to a physician assistant or nurse practitioner you haven’t seen before. That raises concerns about continuity of care and other issues if telehealth isn’t covered in the future with an existing physician practice contract and patients are steered to a platform that is either owned or managed by a health plan.”

Telehealth may not be a boon for doctors, even though it provides a way to easily monitor the health of patients with chronic conditions. “It doesn’t necessarily mean that every one of those telehealth visits is going to be compensated on a fee-for-service basis,” Gilberg said. A practice is more likely to receive some form of capitated payment for each patient, so while the technology makes it easier to check in with patients, that telehealth time won’t necessarily be compensated.

Kishlay Anand, M.D., M.S., founder and CEO of Akos, a telehealth technology company, sees telehealth playing a vital role in managing chronic conditions and reducing medical spending on hospitalizations. “It will become part of the care continuum where, basically, care will start at home,” Anand said. “You will still be able to see your provider and still go to the hospital, but for that high-risk chronic care group, using telehealth and virtual care management is going to be mainstream going forward, and that’s critical to bending the cost curve in health care.”

Advocates for telehealth point to banking as the model health care is following, albeit at a much slower pace. A decade ago, almost all banking was done in person, and today, the simplest transactions are mostly done online with the branches handling more complex needs.

Anand estimates that one-third of visits eventually will be virtual. “Basically, what you are doing is incorporating telehealth as a methodology in the complete care management, and it becomes another access point for patients,” he said.

Ely agrees that 25% to 30% of primary care patients can be evaluated using telehealth with satisfactory outcomes, but work remains to be done. “Physicians are going to have to develop best practices for using this technology, and the use of the technology must be incorporated into medical education,” Ely said. “What is still needed, however, is to ensure compensation is commensurate with the type of service provided.”

Anand adds that telehealth parity laws that many states have passed will help ensure physicians are compensated for virtual visits at the same rate as in-office visits. Telehealth also may be necessary to help with the pending shortage of primary care physicians. “We all know that primary care as a gatekeeper concept works very well,” Anand said. “As health care moves from a churn-and-burn, fee-for-service model to a more value-based model, I think primary care will need to use technology and a virtual high-touch approach to manage the population more efficiently and cost effectively.”

**Is telehealth a worthy long-term investment?**

COVID-19 has boosted the acceptance of telehealth for both patients and physicians, but the unknowns about reimbursement and long-term patient enthusiasm make it a challenging bet for cash-strapped practices. Will the investment pay off?

“It’s definitely going to decline some from where it is right now,” said Jeremy Gabrysch, M.D., founder of Remedy, a virtual care provider based in Austin, Texas. “Providers are going to be…more eager to see patients back in the clinic, and patients might even gravitate toward that a little bit. But I don’t think that we’re going to go back to where we were.”

And moving back to only in-person visits might hurt a practice’s long-term outlook, he adds. “We should be careful about swinging too far back to the old status quo, because there are these younger patient groups who are wanting this kind of virtual care,” Gabrysch said. “And actually, people across all generations have found that telehealth is very convenient and that they still are very connected to their doctor, even when they connect to them by video. We don’t want to lose this opportunity.”

Anand sees a future where physicians can’t ignore telehealth as an option, because it will play a vital role in doing well in value-based care. “Telehealth is going to be critical, and any primary care physician [who] wants to provide better access to care and move toward value-based initiatives needs to look at and invest in telehealth as part of moving from the fee-for-service model,” he said.

Gilberg sees potential, but he believes a lot rides on reimbursement for general acceptance.

“I expect longer term that you might see greater take up again, especially for something [such as] behavioral health, as opposed to other services where you really need to see a patient to maybe do some diagnostic testing,” Gilberg said. “If the patient demand isn’t there, and the payers are not supporting it, it is highly unlikely that physicians and medical practices will be able to supply it because their margins are already small. Once we emerge from the pandemic, telehealth is going to be largely contingent on payer coverage as well as patient demand.”

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Managing COPD patients during COVID-19

by Jordan Rosenfeld Contributing Author

Even before COVID-19 began causing respiratory distress around the globe, experts say the United States was experiencing a respiratory crisis. More than 16 million Americans have been diagnosed with chronic obstructive pulmonary disease (COPD), according to the National Heart, Lung, and Blood Institute, and many millions more may be living with it undiagnosed. Experts have been weighing in on the best practices for treating COPD, particularly in light of the changing restrictions imposed by COVID-19.

“COVID-19 is only highlighting the crisis we have faced previously and helping us ask how do we better treat our patients with these chronic respiratory diseases,” says Laren Tan, M.D., director of the Comprehensive Program for Obstructive Airway Diseases at Loma Linda University Health in California.

Tan says that prevention should be the most important goal for physicians treating COPD, as “we don’t want progression of disease.”

Best practices for diagnosis
Prevention starts with an accurate diagnosis, according to MeiLan Han, M.D., a professor of medicine in the Division of Pulmonary and Critical Care at the University of Michigan in Ann Arbor. She says there are problems with both overdiagnosis and underdiagnosis here in the U.S.

“Many primary care providers don’t order pulmonary function testing,” she says, referring to the spirometry test, the best way to make a COPD diagnosis.

Unfortunately, in the time of COVID-19, pulmonary function tests pose a health hazard because they generate aerosols, which makes the tests challenging to carry out.

Han laments that there is no standard questionnaire to help diagnose COPD as there are for other chronic disorders, such as diabetes, high blood pressure or high cholesterol, other than the COPD assessment test (CAT).

“[Due to COVID-19] it’s as though we’re going back to an earlier stage in medicine where we (don’t) even have the technology of the stethoscope and (have) to focus on what the patient is telling you, what you can hear in their voice and the way they’re talking and breathing,” says Madelyn Rosenthal, M.D., assistant professor of pulmonary and sleep medicine, and codirector of the Martha Morehouse Pulmonary Rehabilitation Program at The Ohio State University Wexner Medical Center in Columbus, Ohio.

She says the difficulty of diagnosing COPD makes it important to do a thorough history of exposures beyond tobacco, including “any environmental exposures such as chemicals, toxins, coal burning stove with poor ventilation, etc.”

Because many symptoms of asthma, bronchitis and COPD overlap, Rosenthal says physicians should “make sure you know what (patients’) triggers are.”

Diagnosis is also made more challenging by the shift to telehealth due to COVID-19. Though telehealth does allow for continuity of care, many physicians agree that it is not ideal for working...
with patients who have COPD. Andrew Martin, M.D., chair of the Department of pulmonary medicine at Deborah Heart and Lung Center in Browns Mills, New Jersey, shared his experience regarding a patient who called in asking for a refill on an inhaler because of increased shortness of breath. He felt he couldn’t determine the man’s condition over the phone and insisted the patient come in to the office. In person, he realized the man was experiencing heart failure. “Telehealth is good for follow-ups but I don’t use it for an initial visit or evaluating unless I know the patient really, really well,” Martin says.

Once a diagnosis is confirmed or known, physicians can begin to make or continue a treatment plan. Martin’s motto is, “Protocols are nice, but they are no substitute for paying attention.” He treats each patient with COPD as an individual case. “Doctors are not paid to check off boxes and click algorithms—spend time with your patients, ascertain whether they are doing normally or abnormally for themselves, or if disease is progressing,” he suggests.

**Smoking cessation**
The most important step in treatment is helping patients cease smoking if they are still smoking, Martin says. That could mean getting them on a medication proven to help, such as bupropion or varenicline, or adding in a nicotine replacement option.

“Smoking itself needs to be thought of as a chronic disease with all kinds of bad health outcomes,” says Benjamin J. Seides, M.D., M.P.H., director of interventional pulmonology at Northwestern Medicine in Winfield, Illinois. “There is nothing we can do for (you) that is as beneficial as quitting smoking, no matter what stage of COPD you have,” adds.

He opts for a harm reduction model. “My philosophy is that if you need to use nicotine replacement for the rest of your life, then use it, because it’s way better than the alternative.”

**Medications and treatments**
After handling smoking cessation, Martin turns to three common types of medication to prevent flare-ups and exacerbations: inhaled steroids to reduce inflammation, long-acting bronchodilators to open airways, and anticholinergics to reduce mucus secretions.

A more recent formulation with fluticasone furoate, umeclidinium and vilanterol offers all three medications in one inhaler, which can improve patient adherence and even outcomes, says Seides.

As research varies on which patients should be taking inhaled steroids, which are linked to an increased risk for pneumonia and other infections, Han recommends checking the blood eosinophil levels for high-risk patients, which will give a more accurate sense of who needs to be on steroids.

For more extreme cases where lungs have been severely affected due to emphysema, some patients may qualify for valve placement, Han says. “Emphysema destroys the natural elasticity of the lung, so it’s like a really old rubber band. By taking diseased tissue out you provide more room for the diaphragm to move the lung up and down, and the valve helps the lung de-gas,” she says.

Yet another new treatment is currently in phase three clinical trials, known as targeted nerve denervation, explains Seides. “(It’s) a bronchoscopic therapy where you burn the vagus nerve to reduce vagal tone to the lungs, which helps treat the chronic bronchitis phenotypes.”

Lastly, Tan encourages physicians to remind their patients of basic lifestyle behaviors such as exercise, at whatever capacity they are capable and healthy diet.

When patient adherence is an issue, David Hatfield, D.O., chief medical officer of Hatfield Medical Group, a family practice in Arizona, likes to give his patients a vision of what their health can look like months down the road if they stick to their treatment plan. “Remind them that while COPD is not curable, it is reversible.” He also encourages learning more about the barriers to patients’ ability to stick to a plan. “Maybe they have a friend that took a medicine that didn’t sit well with them and now they don’t want to try it,” he says. “Listen to them, understand their concerns.”

**Reimbursement and revenue**
Keeping patients with COPD healthy also goes a long way toward improving quality metrics that may affect a physician’s reimbursement. Medicare penalizes physicians whose patients are readmitted to the hospital within thirty days of a discharge.

“The minority ends up costing the majority of health care utilization. The goal is to reduce that utilization, especially during COVID-19,” says Tan. Han’s health system established a transition-of-care clinic that follows up with anyone who has been hospitalized for COPD exacerbation or flare within 7 to 14 days of discharge. Smaller practices could hire a care coordinator, Hatfield recommends.

Moreover, helping patients with COPD stay healthy can minimize what Tan calls the downstream costs of health care on clinic staff, who could be doing less calling and follow-up.

“No outcomes, no income,” Hatfield concludes. —

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MANAGING COPD / CHRONIC CONDITIONS

**Managing COPD**

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CODING INSIGHTS / CHRONIC CONDITIONS

Coding case studies

COPD

by Renee Dowling, CPC Contributing author

In the medical billing and coding field, getting paid requires accurate documentation and selecting the correct codes. In our Coding Case Studies, we will explore the correct coding for a specific condition based on a hypothetical clinical scenario. This scenario involves a patient presenting with symptoms of chronic obstructive pulmonary disease (COPD); see if you can choose the correct codes.

Clinical Scenario

History of Present Illness

Cough

Episode onset: over the last week. The problem has been gradually worsening. The cough is nonproductive. Associated symptoms include rhinorrhea, a sore throat, shortness of breath and wheezing. Pertinent negatives include no chest pain, chills, fever, headaches or myalgias. Symptoms are aggravated by lying down. Patient has tried a beta-agonist inhaler for the symptoms. The treatment provided no relief. There is no history of pneumonia.

Patient denies any history of lung problems. Had this same issue in September treated with Medrol Dosepak (methylprednisolone) and azithromycin. In October, the same issue was treated with Medrol Dosepak and Augmentin (amoxicillin and clavulanate). Wife states that patient has had moderate relief with past treatment but breathing problem has not completely gone away.

Review of Systems

Constitutional: Positive for fatigue. Negative for chills and fever

HENT: Positive for congestion, rhinorrhea and sore throat. Negative for sinus pressure, sinus pain and trouble swallowing

Respiratory: Positive for cough, chest tightness, shortness of breath and wheezing

Cardiovascular: Negative for chest pain and leg swelling

Gastrointestinal: Negative for nausea and vomiting

Musculoskeletal: Negative for arthralgias and myalgias

Neurological: Negative for dizziness, light-headedness and headaches

Psychiatric/Behavioral: Negative for confusion
Physical Exam
Constitutional: Patient is oriented to person, place and time.
Head: Normocephalic and atraumatic
Cardiovascular: Normal rate
Pulmonary/Chest: Accessory muscle usage present. He has wheezes in the right upper field and the left upper field. He has rhonchi in the right middle field, the right lower field, the left middle field and the left lower field.
Neurological: He is alert and oriented to person, place and time.
Skin: Warm and dry
Psychiatric: He has a normal mood and affect. His behavior is normal.

Assessment and Plan
1. COPD with acute exacerbation
   - DuoNeb (ipratropium-albuterol) 0.5 mg-3 mg (2.5 mg base)/3 mL nebulizer solution; 3 mL doxycycline hyclate 100-mg tablet; Deltasone (prednisone) 20-mg tablet
   - Patient given nebulizer treatment in clinic. Lungs improved, but still have expiratory rhonchi and wheezes. Patient reports breathing is easier but still somewhat tight.

Documentation
Coding Requirements
1. With
   - acute lower respiratory infection
   - acute exacerbation
2. Unspecified

- Code also type of asthma, if applicable (J45.-)

Use additional code to identify:
- exposure to environmental tobacco smoke (Z77.22)
- history of tobacco dependence (Z87.891)
- occupational exposure to environmental tobacco smoke (Z57.31)
- tobacco dependence (F17.-)
- tobacco use (Z72.0)
- Code also to identify infection

Renee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Indianapolis. Send your diagnosis coding questions to medec@mjhlifesciences.com

DIAGNOSIS CODE

J44.0  ➤ Chronic obstructive pulmonary disease with (acute) lower respiratory infection

J44.1  ➤ Chronic obstructive pulmonary disease with (acute) exacerbation

J44.9  ➤ Chronic obstructive pulmonary disease, unspecified
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HELP PROTECT YOUR ADULT PATIENTS. TAKE THE SIMPLE STEP OF ADDING Tdap TO YOUR VACCINATION PROTOCOL.¹

Help close the Tdap gap

• CDC recommends that all adults 19 years of age and older who have not previously been vaccinated with Tdap receive a dose of Tdap¹

• However, only 31.7% of eligible adults in this age group are vaccinated with Tdap as of 2017²
  – By comparison, the rate for adult influenza vaccination for the 2016-2017 season was 45.4%²
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BDJRNA200001 July 2020
Produced in USA.
As the COVID-19 pandemic and shutdown kept people at home to avoid getting sick, especially those with chronic health conditions, experts recommended remote patient monitoring (RPM) as a solution to continuity of care. With forethought and the right technology on board, RPM can be a good complement to telehealth, allowing physicians to receive data about their patients’ in real time.

The most commonly used RPM devices track essential vital signs such as blood pressure, heart rate, blood glucose levels, oxygen saturation and temperature. There are also RPM devices for nervous system signals, weight, patient activity and sleep.

“As we gain more experience with RPM, we’ll figure out even more clinical conditions that it can help us with,” says Richard L. Seidman, M.D., MPH, chief medical officer of L.A. Care Health Plan.

In fact, his practice has been using RPM in a prenatal pilot to reduce the number of times pregnant women visit their doctor’s offices in person. Women in this pilot take their blood pressure and weigh themselves daily at home, then transmit that information to their doctors.

Physicians at the leading edge of RPM have adopted remote spirometry for to monitor patients with chronic obstructive pulmonary disease (COPD) and asthma, a population at high risk for COVID-19.

A big benefit RPM is that many systems don’t need to rely upon patient reporting their data. This is especially helpful for patients with conditions such as diabetes, which are subject to many incremental changes between physician visits. With RPM, crucial data can be transmitted to the doctor instantly, such as medication adherence and A1c.

RPM cannot replace in-person clinical visit, but it’s an essential tool alongside taking a good history, says Abe Malkin, M.D., MBA, founder and medical director of Concierge MD LA, a concierge practice.

“In primary care, once you have a really good history, you can almost make your determination. You use the physical exam to confirm that diagnosis. So [RPM] is sufficient to make diagnoses with a high level of comfort,” Malkin says. “It won’t replace in-person visits, but as we get more comfortable with it, it will give better access to care.”

Seidman adds that RPM is a great complement to telehealth, which is quickly becoming the standard for seeing patients during the COVID-19 pandemic.

Considerations for adopting RPM

For physicians who wish to begin adopting RPM or increase its usage in their practice, “the first thing is to define the highest yield monitoring that you think you need to do as part of your practice,” says Joel Klein, M.D., senior vice president and chief information officer at the University of Maryland Medical System in Baltimore. “Really define what problem you’re trying to solve.”

For physicians who have a large chronic care population, it may be wise to start with just one, he says. Let’s say a physician chooses monitoring blood glucose. It’s important to use an RPM technology that allows a physician to see the big picture of the data, Klein says. “You need the ability to get insights from it.”

With insights, however, comes responsibility,
Klein says. This RPM may show danger signals such as a patient who is hypoxic or with a dangerous blood sugar level. “What are you going to do with that information?” he asks. Physicians need to think about their obligation and how to set the patient up for success.

In order to access the RPM data, most physicians will need a telehealth platform that interfaces with their EHR. A physician’s vendor can help find the best platform to sync with the EHR, Malkin says.

Identifying the patient populations a physician will treat with RPM also is critical to narrowing the software or platform choice. “I would start with taking patients who feel their symptoms lend more to a telehealth exam,” Malkin says.

Additionally, Malkin suggests physicians look for RPM technology that is easy for patients to use at home, whether it be a blood pressure cuff, glucose monitor, pulse oximeter or another device.

**RPM revenue benefits**

RPM may offer an increased revenue stream for physicians whose income is negatively affected by COVID-19. Medicare waivers have made it possible for physicians to bill for services done remotely without having to bring patients in.

Additionally, many of the platforms may help physicians defray costs early on by taking a higher cut of the revenue, but eventually physicians can increase their revenue.

Physicians may not be aware of how many aspects of RPM are reimbursable, as well, says Adam Powell, Ph.D., president of Payer+Provider Syndicate, a Boston-based health care consulting firm.

RPM codes include:

- Initial setup of the device and patient education: 99453.
- An additional code that can be billed each 30 days for supplying the device: 99454.
- 20 minutes or more of clinical staff, physician or other qualified health professional time in a calendar month requiring interactive communication with the patient or caregiver: 99457.
- Collection and interpretation of physiological data digitally stored and transmitted to the patient and/or caregiver, to the physician or qualified health professional: 99091.
Learn from a medical practice that reopened during COVID-19

If resuming clinical operations during a pandemic were as simple as flipping a switch and welcoming patients back, health care providers across the country would be in a very different situation. COVID-19 has completely upended clinical operations, requiring a “new normal” going forward.

As you develop a plan for successfully resuming operations, you’ll need to answer many fundamental questions. How will I keep patients safe? How will I protect my staff? How many staff do I need? How can we leverage data to be nimbler and more responsive? Centers for Medicare & Medicaid Services and the American Medical Association have published helpful guides on restarting nonemergency clinical care.

The reopening experiences of a high-volume outpatient clinic can provide several valuable lessons. This clinic focused on three principal areas of importance: safely serving patients, ensuring staff safety and resuming operations.

Keeping patients safe
Patient safety was the top priority. The clinic quickly established a robust pre-screening process to keep individuals who may have been exposed to or were experiencing symptoms of COVID-19 away from the outpatient setting, and triaged them to a COVID-19 screening center. The pre-screening also incorporated scripting that allowed the clinic’s staff to communicate to patients any changes that had been implemented to keep them safe.

Initially this pre-screening process was entirely manual and involved the time of countless staff members. The clinic’s goal was to transition as much of this screening to digital as possible. A two-phased plan was developed to bring patient pre-screening online after just six weeks, more than half of the clinic’s patient pre-screening was being done electronically. This enabled staff to do additional work with patients in the clinic and spend more time on the phone with patients who reported positive symptoms during the pre-screening process.

Understanding the importance of rapid communication to patients, the team quickly revamped an existing website and repurposed it to provide critical updates for patients. This included information on visitor restrictions, changed hours of operation and facility changes to maintain social distancing, as well as the clinic’s enhanced cleaning protocols.

Most critical in terms of patient safety were the changes the clinic made to scheduling, which ensured patient appointments did not overlap and that there would be ample time between appointments to clean equipment and shared spaces. The clinic’s prior scheduling templates were modified and reduced by 30%, subsequently extending the clinic’s hours to accommodate a volume comparable to pre-COVID-19.

Ramping up clinical capacity also meant thinking differently about keeping staff safe while also providing care. The same safety measures for patients were also applied to staff, such as requiring wearing of masks and social distancing. For clinic staff, physical distancing proved the most challenging, as staff had previously worked in close proximity. To counteract this, the clinic began staggering staff schedules and placed limits, based on office square footage, on the number of staff members.

The clinic also established an all-staff screening program for exposure to COVID-19 and symptoms of COVID-19, similar to the one used for patients. The clinic is investigating the feasibility of testing for all of its frontline workers.

Reviving operations
While patient and staff safety were the clinic’s priorities, there was still a need to provide clinical care and resume revenue-generating activities. After severely minimizing its clinical activity to only the most urgent of patient cases, the department faced a significant backlog of outpatient appointments that had been canceled. The combination of rescheduled appointments and new volume could not fit within the newly reduced capacity. The clinic began using patient visit data to determine appropriate staffing levels and created dashboards to project volumes and hours of operation to match demand and revenue requirements.

With daily operational changes in the clinic a new norm, daily huddles enabled staff members to assess what was working well and what needed to be changed. These daily huddles allowed staff members to respond more swiftly to quickly changing operational dynamics.

Liz Aron is a consultant with Freed Associates, a California-based health care management consulting firm. Send your practice management questions to medec@mjhlifesciences.com.
Practice valuation:
How much is your practice really worth?

by Todd Shryock Managing Editor

Physicians who have spent most of their working life building a practice often have no clue how much their business is worth. This lack of knowledge can affect retirement planning, create financial delays when applying for loans and allow inefficiencies to erode the overall value of the practice.

“I believe doctors should have this information so they know what their business as an asset is worth,” says Vincent M. Brinly, the CEO and director of valuation services at the Practice Valuation Group. “More often than not, it’s their most important asset; they need to know how to make it better, if possible.”

Knowing the value allows doctors to protect their investment with different forms of insurance that accurately reflect the total worth of their practice. Another advantage to having an accurate valuation done is to better connect a retirement plan that relies on the proceeds from a practice sale to the reality of the market.

“What someone thinks a practice is worth and what they can sell it for (are) sometimes different—and sometimes that difference can be a wide chasm,” says Brinly. “That’s why getting it valued by somebody who doesn’t have the blood, sweat and tears invested in it and is looking at it pragmatically from a third-party perspective is important.”

Getting started

Experts agree that the most important decision is who to hire to perform the valuation. Although there are several industry designations (see sidebar) to help identify people with the right training, it is important to ask a lot of questions before hiring a professional.

“Make sure they are health care specific, because business valuation can range from valuing restaurants to retail and all kinds of other industries,” says Valora Gurganious, MBA, CHBA, a partner and senior
tors and nonphysician providers. Examine all the contracts with doctors, patients are coming from, and review where existing and new residual value.”

“Clearly, they’ll be valuing the tangible assets of the practice, which would include furniture, fixtures (and) equipment—both medical and business—including how it’s been depreciated and if there is any residual value.”

Brinly says that the analyst will review where existing and new patients are coming from, and examine all the contracts with doctors and nonphysician providers.

“They’ll take all that information and compare the practice to benchmarks to see how they compare to their peers in certain metrics,” says Brinly. “We come to a decision on what’s going right with the practice, what’s going wrong and how that affects value.”

The entire process from start to finish usually takes about four to six weeks. Typically, there is a site visit, which may include additional interviews with key employees, such as a practice manager or other physicians. When the process is complete, the analyst will provide a report that explains how the final valuation number was reached, and what can be done to increase the value.

Valuation costs can be a percentage of the valuation, hourly charges for time spent calculating it, a fixed fee or some combination of these. Brinly advises making sure costs and budgets are clear before the process starts.

Circumstances matter
The reason the valuation is being conducted can change the time and scope of the process. For instance, if a small practice is being sold to another physician because the current owner is retiring, the commitment of the remaining employees is important, as is a transition plan to introduce patients to the new owner.

“The owner may provide some kind of incentive to stay once the practice is sold,” says Gurganious. “Maybe (the employees are) offered a bonus at the end of 12 months after the transition of ownership — anything to keep the stability so the new owner has confidence that the practice will look the same or better than before. They don’t want to worry about half the talent walking out the door.”

Likewise, with patients, transition time can add value for the buyer of a smaller practice where the goodwill relationship between doctor and patient is the main asset. “There has to be a proper transition plan set up where the doctor selling is going to introduce the buying doctor to ensure patients continue to flow to the practice,” says Brinly.

“If you don’t, then there’s really not much value and that unfortunately plays out when doctors haven’t prepared. The timing of the valuation is very important.”

If retirement is the selling doctor’s goal, the earlier the valuation, the better, as it allows time to fix inefficiencies and to sell before the value declines. “I’ve had many doctors come to me and say they are ready to get out and hang up the stethoscope, but they are down to two half-days a week,” says Brinly. “There’s just not a lot to sell there. (They have) to plan out when it’s time and when they want to get out.”

For practices receiving an offer of a buyout from a hospital, an asset-only valuation may be performed, which looks solely at the tangible assets and not the doctor’s goodwill with patients, says Randy R. Bauman, the CEO at Delta Health Care, which advises both hospitals and physicians on sales transactions. Although having your own valuation done to compare it with the hospital’s offer may make sense, for smaller practices, the cost of the valuation may exceed any impact on the selling price.

“Physicians should remember that the hospital’s valuation isn’t subject to negotiation,” says Bauman. “They are limited to the value determined by their independent appraiser. Valuations can be updated to correct errors in the data provided (by) the appraiser, reflect additional information, reflect changes in quantities and other pertinent information, but a negotiation between two competing valuations is not going to happen.”

For physicians going through
a divorce proceeding, separate valuations may be performed with one expert representing each side. However, according to Gurganious, it is common to have both sides agree on which expert to use with the stipulation that both sides will accept the findings.

**Increasing value**

If a physician plans on selling the practice, maximizing its value becomes paramount. A valuation report will indicate which areas need the most help, but there are steps a practice can take to increase its value now.

Gurganious recommends taking at least a year to start implementing plans that will increase profits. “You are always going to be more attractive if the cash that the practice kicks off is higher, so any ways that expenses can be reduced or new service lines added, that should be done,” she says.

Aesthetic lines that can be run by nonphysicians can be an attractive addition to a practice buyer, as is subleasing unused space. Make sure the structure of the practice is set up so that the practice can run without the physician doing everything. “If they’ve got a strong management team, a strong clinical team, and everyone operates like a well-oiled machine, that is highly valuable to someone acquiring the practice because they can come in on day one and just fit right in and begin to make money,” says Gurganious.

And don’t forget about the obvious items that can make a bad first impression on both patients and buyers: walls that need painted, outdated flooring, a poorly designed website and equipment in need of repair. “Nobody wants to buy something that’s rundown,” says Gurganious. “Take that year and get the house in order, and from a fiscal standpoint, driving revenue is key, as is reducing expenses as much as possible.”

Experts say physicians need to be prepared for a valuation that may be lower than what they personally think it’s worth, especially those doctors running smaller practices.

“I think it’s understandable, because they have put in all of those decades’ worth of work,” says Brinly. “They started it from nothing, or they bought it from another doctor who was retiring and spent the next 30 years building on that.”

“I remind my physician clients that, in general, whatever value they have created through their hard work, they have taken home in compensation and profits over the years,” says Bauman.

By creating goals and timelines, physicians have more time to get the best return for their hard work.

“A practice has more value when you plan ahead,” says Brinly. “Selling the practice in the declining phase of its life cycle is not going to net you as much value as selling it in the growth or mature phase. The more you plan and get the valuation done early, the more time that you can make course corrections to increase that value.”

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**Valuation credentials**

When it comes to valuation experts, there are several designations that can help physicians decide who can best handle the analysis of their practice. Here are the designations and a brief description of what it takes to attain them.

**Accredited Senior Appraiser**

Must have over 100 hours of education and five years of full-time valuation experience; required to submit a detailed final analysis for peer review.

**Chartered Financial Analyst**

Must undertake extensive training and three years of exams, and demonstrate industry experience before applying.

**Certified Valuation Analyst**

Must pass an exam and have two years of full-time business valuation experience; required to submit a written report that is reviewed by their peers before being granted the designation.

**Accredited Business Valuation Specialist**

Must complete 75 hours of education and have 50 hours of business valuation experience; accreditation issued by the American Institute of Certified Public Accountants.

Experts agree that designations are important, but overall experience in health care and specifically the specialty the physician works in is the principal factor when choosing a valuation expert. The physician should ask lots of questions about the expert’s experience with similar practices before making a decision and not rely solely on the designations above.
Why tax planning matters for your retirement

Despite recent pressures on physician profit margins, a physician’s income remains relatively high compared with that of the general public. Without the proper tax planning strategies in place, a physician could face some costly surprises.

Understanding taxation
In 2020, a physician filing a joint tax return with taxable income exceeding $414,701 is taxed at the 37% federal tax bracket, which goes to 37% if taxable income exceeds $522,051. The physician would also be subject to Social Security, Medicare and state income taxes, as well.

For most working physicians, the majority of their income will come from their paycheck or practice revenue. In retirement, though, physicians will likely rely on multiple different sources to generate income including investment income, IRAs, social security, and possibly even pension plans. Each type of income incurs different tax liabilities and will affect your “take-home” amount in different ways.

For example, contributions made to traditional retirement plans with pre-tax dollars during your working years will be taxed upon withdrawal in retirement as ordinary income, but Roth IRA contributions made with post-tax dollars will not be taxed when withdrawn. A portion of your social security benefit is taxed based on your overall income (from 0%-85% of the benefit), which means physicians’ benefits will likely be heavily taxed.

Understanding how your retirement income will be generated will give you an overall plan for how to withdraw the funds with the least amount of tax liability chipping away at your resources. It will also allow you and your financial adviser to plan ahead — working to avoid becoming “tax deferred” rich and owing a huge chunk of change each year in retirement.

Capital gains & tax-loss harvesting
When selling a security, the tax rate on the gain in a taxable account is determined by the length of time you have owned the security. Since selling securities may be part of your drawdown plan for generating retirement income, you’ll need to know at which rate your securities will be taxed.

Long-term capital gains are taxed up to 20% depending on income, and short-term capital gains are taxed as ordinary income, which could be as high as 37% depending on your marginal tax bracket. A security qualifies for long-term gains when it has been held for over a year.

Sometimes, it may be advisable to take tax losses to offset capital gains elsewhere. This is known as “tax loss harvesting” and involves the selling of certain investments that show a loss in order to offset the high capital gains rates on other securities being sold or taxed that year.

Be aware of the “wash sale rule,” which prohibits individuals from claiming a loss if the same or substantially similar security is purchased within 30 days of the sale.

Maximize contributions
Other tax-minimizing strategies are related to the practice retirement plan, and thanks to provisions of the 2019 SECURE Act, can now be implemented both in the accumulation and decumulation phases so long as the physician is earning wages from noninvestment income. Physicians should maximize their annual contributions to their retirement plans to:

- adequately prepare for retirement;
- variegate their retirement income between tax-free, tax-deferred, and tax-advantaged accounts;
- and lower their taxable income during their working years.

In 2020, physicians under 50 can contribute $19,500 each year to their 401k accounts while physicians over 50 can put aside that same amount plus an additional $6,500 each year, which makes them able to contribute a total of $26,000 to a 401k annually. Paring a 401k with a profit-sharing plan can further increase the annual contribution to $57,000 for those under 50 and $63,500 for those over 50.

Any amount that is contributed to a 401k is made with pre-tax dollars.

In previous years, physicians could only continue contributing to their IRAs until age 70½ when they were forced to begin taking Required Minimum Contributions (RMDs). However, the 2019 SECURE Act both extended the RMD age to 72 and eliminated the curtail on making contributions.

One caveat: the physician can only continue to make contributions past this date if he or she shows earned income not generated from investment accounts. This change will especially benefit those individuals who continue to work past age 72 in some fashion and allow a tax deduction for contributed funds.

Julianne F. Andrews, MBA, CFP, AIF, is a principal and co-founder of Atlanta Financial Associates. Send your financial questions to medec@mjlifesciences.com
Specially in uncertain times, it is crucial for physicians to build a plan that protects their financial future. Creating a solid retirement plan can build peace of mind as you navigate the challenges of practicing medicine today. So what should you be doing?

Medical Economics® sat down with Joel Greenwald, M.D., CFP, president of Greenwald Wealth Management in St. Louis Park, Minnesota, to discuss important tips for physician retirement planning. This interview has been edited for length and clarity.

Medical Economics®: Why do many doctors seem to have trouble saving for retirement?

Greenwald: I would say that is multifactorial. First off, I don’t think that difficulty saving for retirement is limited to physicians. There are certainly plenty of other highly paid folks who don’t do a good job of saving for retirement. Spending money is fun. You know, having a big beautiful house is fun. Driving a fancy car is more fun than a run-of-the-mill car. Eating out is a big expense that we see. And the even bigger one is travel, travel to Europe, travel to Asia. So spending a lot and not being a good saver is just, I think, part of our culture.

Maybe something that’s unique to physicians is the pent-up demand after all the years of training. You know, the four years of medical school, at least three years of residency, possibly more fellowship. Doctors come out with the desire to keep up with their peers who maybe didn’t go to medical school. Or after making $55,000 a year in training, now they go up to a salary that’s four, five, six times or more than they were making as a resident. They want what’s due to them.

Part of it for physicians, and Americans in general, is we don’t do a good job in this country of providing financial education. And it doesn’t get any better in medical school or in residency or fellowship. Doctors just don’t learn this stuff.

Another thing that plays into it is that medicine is a helping profession. For some reason, the idea of helping people and thinking that money is important seem to be contrary ideas. And so a lot of physicians say to themselves, “I went into this to help people. And I’m going to ignore the money side.” It doesn’t mean that they need to be greedy, but certainly one should understand what’s going on with their money.

I would say another thing that plays into this, and, again, it’s not unique to physicians, is family of origin. We see people who grew up without a lot of money; they can take one of two paths forward. One is that they’re good about saving, maybe they don’t even spend enough. On the other hand, some people make up for the fact that they had deprivation when they were growing up.

Maybe the last thing is that saving money takes hard work. And the hard work that it takes is understanding where your money goes. A lot of doctors just don’t bother to take the time to understand where their spending is going. And they figure it’ll take care of itself or they’ll just continue to make a nice income. So they think there will never be a day of reckoning. And obviously, the day of reckoning...
is the day that they decide maybe they want to cut back. Maybe they don’t want to practice anymore. Maybe they’re not able to practice anymore. If they haven’t been doing the savings, that’s going to come back to hurt them.

ME: What percentage of their work income should doctors aim to replace when they retire?

Greenwald: What we look at is how much a physician wants to be able to spend in retirement. And I would break this into two different cohorts. The first cohort is young and mid-career physicians. It’s very hard for those folks to get a handle on how much they want to be able to spend in retirement. If you were to ask a 40- or 45-year-old doctor, “How much do you want to be able to spend in retirement?” they don’t have a clue, nor really should they. That’s why at our firm, we use the 20% of gross income rule. As long as our clients are saving 20% of their gross income, we’re confident they will be on track to retire.

I’ve been doing this for more than 20 years. So I’ve had a chance to see how some of this stuff turns out, you know, the doctors who saved 25, 30, 35%, they’re in great shape. They can cut back when they want, they can retire when they want. The ones who were saving 10% don’t get to retire.

As far as the replacing income idea, sometimes we’re asked, “What number do I have to accumulate and then I can be done working?” And that obviously varies for everybody. We have clients who spend $4,000 a month in retirement, and they’re perfectly happy. And when we point out to them, “You could afford to spend a lot more than that,” they say, “No, we’re doing all the things we want to do, we’re enjoying life, spending more money would not bring us greater joy.” We have other clients who spend $20,000 a month.

Once people get closer to retirement, then it’s possible to run accurate retirement projections, because they have a good sense of what their baseline spending is. On top of that baseline spending, we break out health care as a separate expense, because we want to inflate that faster than regular inflation. We usually set aside a vacation bucket that runs until age 80. In our experience, a lot of our clients have pent-up desires to travel, and then at age 80 that gets cut back.

So I guess it varies based on where they are in their life cycle. For younger doctors, saving 20% is good. If they’re behind on their retirement savings, then it should be more than 20%. And for those closer to retirement, we can run a real robust financial plan to tell them where they are.

ME: What are some of the savings plans that are available to doctors?

Greenwald: Most doctors are going to be familiar with the 401(k) or the 403(b) plans that they have at work. For those under age 50, they can put away $19,500 a year. And for those 50 and older, they can put in $25,000. All doctors, in my opinion should be maxing out their retirement savings vehicle.

One thing that we’ve been seeing is more and more retirement plans are allowing after-tax contributions to the 401(k) or 403(b). Traditionally, it was only pretax money you could put in, but now you can put in after-tax money. For younger physicians, who are under 40, we have them do after-tax Roth contributions to the 401(k). So no tax advantage now. But on the back end, they don’t have to pay any tax.

ME: Are you finding clients talking about retirement at a younger age?

Greenwald: No. I know we all read about burnout and discontent. I don’t see people trying to get out early. What I will say is, I sometimes will have a client say to me, I need to be done at 60, and the numbers just don’t work in their case. What is very common in those cases is they work full time until 60. And then they cut back to 80% or 60% of an full-time equivalent. They try to work in the areas of their practice that they like better, and get rid of the parts they don’t like.

Doing that for three or five or seven years is incredibly powerful in that they’re happier. And they’re continuing to build their nest egg.

I have a client who has been working with me pretty much since I started in this practice. And at age 50 she went to half time, and now at 60 she just recently retired. And she told me the best thing she ever did was going to half time because she’s been able to do all the things that she wanted to do. I can tell you, my clients who go even to 90% of full time, they are so much happier. Their lives are much more their own. »

Check out Medical Economics pulse. This interview was transcribed from a video interview that was recorded as part of Medical Economics® Pulse video program.

Check out more video interviews with experts at bit.ly/MedEcVideo.
Many physicians are disenchanted with traditional practice models. Payer hassles and the fee-for-service hamster wheel often leave physicians burned out and unable to spend enough time with their patients — the reason they pursued medicine in the first place.

In response, some physicians have chosen to transform their practice into a concierge model. In this special section, brought to you by Medical Economics® and leading concierge medicine companies, we introduce you to physicians who have already made the leap to concierge medicine, and discuss with them why they made the transition, how they overcame challenges, and where they found success.
What my practice was like before concierge

We had a thriving, busy, exciting, action-packed, solo, freestanding, independent internal medicine practice that had been built over the previous 13 or 14 years. We had plenty of patients, but very little time to see them.

We were actually doing extremely well. In fact, when I sat down with some of the concierge companies over the years, the numbers looked just fine. And the question was, “Why do you want to go into concierge medicine [when] your practice is thriving?” And my response was, “There’s just not enough time to see folks. We may be doing well here, but we’re still living in a world of corporate medicine.”

When I practice internal medicine, I feel like I need a little bit more time maybe than a specialist who can zoom from room to room with two or three medical assistants at their side. Pre-COVID-10, we sat down here in the office and had a lot of face-to-face time with patients. I found that with a volume practice, we just didn’t have the time to do that.

Why I decided to explore concierge medicine

It was time. Like I said, we were running a thriving practice. But the only way to sustain that was to keep seeing more and more patients every day. And that was not a sustainable model — it may have been sustainable on paper from a dollars-and-cents standpoint — but from a general well-being standpoint, and being actually able to practice the kind of medicine that I want to practice, it wasn’t.

The benefits I’ve experienced from transitioning to concierge medicine

It’s night and day. I have time now. It’s a bit difficult to compare because the practice models are completely different. A concierge practice is not the same as a volume-based practice. There’s time to talk to folks. Particularly as we moved into the COVID-19 era, I don’t know how having thousands of patients on the books would have worked, as opposed to having a whole lot less than that on the books to communicate with that many people remotely. Because, as
you know, we’d gone completely remote, and now we’re integrating people into the office very carefully.

But when COVID-19 hit, we were ready, because the video conferencing was already in place. People already had my personal cellphone number, people already had my direct email address, people already connected with us on our EHR system, so that they could message the office. We were set. And it worked.

The biggest challenge I faced during my practice transition

It’s a huge leap of faith. Not a lot of people talk about that. It’s a huge leap of faith going from what you’re familiar with, what you’ve built over the majority of your career, and saying to yourself: “OK, I’m going to risk it all. I’m going roll the dice and see if people are going to do this.” You’re counting on that relationship that you have with folks, to be that glue that keeps them connected. And some people value that relationship and see the value in staying on with a physician such as myself. Others don’t. And I totally understood that.

But a personal challenge was getting to the point to understand that there’s a lot of rejection involved in going into a concierge medical practice. And learning that it’s not a personal thing is important. People are making decisions based on what they value and how they handle their health care, and I respect that. So we had to say goodbye to a lot of people who didn’t want to stay on board, which was difficult. That was a challenge.

But even some people who initially said no, ultimately said yes. In fact, now a year and a half later, we’re now seeing folks who initially said no saying yes, so the door is not closed.

“When COVID-19 hit, we were ready.”

If I could do the practice transition again, what would I do differently?

Gosh, I don’t know that I would do anything differently. I think the process that Castle Connolly has laid out is excellent. They have tools that are at your disposal for connecting with individuals, if you want to use them.

The main ingredient, at least in my opinion, was having the right member adviser here on site helping with the transition.

How concierge has affected my feelings of burnout, work-life balance and career satisfaction

I’m off the hamster wheel, I can say that confidently. My career satisfaction is off the charts. I’m much happier than I used to be. And I’m not only just happy with the time I have to spend with people here in the office. I can do the kind of job I want to do as a physician. It’s really not just the nuts and bolts of medicine, it’s really the building the relationships of medicine and getting to know people. And you can’t do that in five minutes, seven minutes or 10 minutes, when you’re trying to get to the next patient or thinking about the two or three other patients in other rooms. I’m going to take up some hobbies because I have so much free time now.

Why I chose my concierge vendor

It was probably summer of 2018, and I received a postcard in the mail from a Castle Connolly Private Health Partners. I looked at it and said, “I don’t know these guys,” and I threw it away. Then I received another one, and said, “Maybe I’ll check them out.”

It didn’t take long for me to realize this was a small company and they were people who were dedicated to what they were doing. I felt very comfortable, as I got to know them, that this was a perfect match, not only from a business standpoint, but from the offerings that were there.

I like to tell people these days, we were doing telehealth before telehealth was cool. That was always part of the model. So, along with that, was health coaching and the benefit of having a personalized health coach who can help patients meet their health goals from weight loss to sleeping better, to dealing with anxiety better, just someone to help you along and coach you on a regular basis. And that was not something I heard anywhere else; that was very appealing to my style.

My advice for physicians considering concierge

Find the right partner and know who’s out there. If that right partner means doing it on your own, then do it on your own. Concierge is certainly a way to stay independent in a world of corporate medicine. It’s a way to be able to be yourself, to practice the way we were trained to practice, to have relationships with people. That’s how I envisioned practicing. And that’s how I’m practicing now.”
Serving patients, sleeping better: How I transitioned my family practice

I was introduced to family medicine at a young age. In fact, some of my earliest memories include running through our doctor’s house trying to avoid my vaccine injections. Perhaps this influenced my decision to become a family physician. About 30 years ago, as a newly minted M.D., I went into practice in Morristown, New Jersey. At the time, opening a traditional practice and accepting insurance were just the way things were done.

But after a while, I realized this model failed to give me the flexibility to develop the physician-patient relationships I was used to from my childhood.

I decided to try a hybrid concierge model. Some patients would pay a premium to get more “concierge” access and services — and others would continue as regular patients. Unfortunately, this hybrid approach to concierge medicine didn’t feel quite right, either.

But after a while, I realized this model failed to give me the flexibility to develop the physician-patient relationships I was used to from my childhood.

I decided to try a hybrid concierge model. Some patients would pay a premium to get more “concierge” access and services — and others would continue as regular patients. Unfortunately, this hybrid approach to concierge medicine didn’t feel quite right, either.

In fact, it felt unethical that the business forced me to offer higher-end service and amenities to some of my patients just because they were willing to pay more. It didn’t sit right with me, so I ended up offering all of my patients the same concierge level of care — even though it meant I was only sleeping four to five hours a night.

I was burning the proverbial candle at both ends, so when a corporate opportunity presented itself, I jumped on it. I thought this new position would offer me a way to slow down and have time with my patients, but I found myself once again seeing 20 to 25 patients a day. There’s just no way to adequately care for a patient in a seven-minute appointment.

I wondered if I’d ever find a more sustainable way to practice — or if I should just consider retiring.

After a winding search for a model that was holistic and sustainable for both myself and my patients, I finally came across Castle Connolly Private Health Partners (CCPHP). I decided to give them a shot.

We hit it off right away. I was sold when I heard how I’d be able to practice the relationship-based medicine from my childhood, offering all of my members benefits such as same- or next-day appointments and a 24/7 connection to me. I couldn’t wait to transition to a full membership-based practice.

The CCPHP team helped make that transition easy and seamless. Now with a smaller panel, I spend all the time I need with each member without having to work until 9 p.m. When I feel it’s necessary, I can spend half an hour, an hour — even an hour and 15 minutes — with a member to get to the bottom of their ailments. I have time to research issues that are affecting my patients.

I even have the flexibility to make some house calls. And Bentley, my 15-pound, hypoallergenic cockapoo, accompanies me on all of my house calls. He’s proud to help out in his role as therapy and emotional support “dog”.

Ultimately, my attitude toward medicine is a holistic one, consisting of body, mind and spirit. That aligns perfectly with the philosophy at CCPHP. My members and I receive access to a variety of health and wellness resources, such as the SENS Solution Wellness Program and personalized health coaching. I’ve already participated in some of these offerings.

But even with all of the amenities from CCPHP, I still run my practice as I see fit, including employing the same staff my patients have grown to know and love over the years. CCPHP is there to support us all, but, ultimately, their concierge model allows me to practice medicine the way I want. And I can finally get some sleep.

I still run my practice as I see fit, including employing the same staff my patients have grown to know and love over the years.

Thomas S. Ziering, M.D., FAAP, is a family physician in Morristown, New Jersey.
Considering retiring or selling your practice?

Think again.

Are parts of your practice becoming too much to manage? Are you thinking of selling your practice before you’re ready because you see this as the only avenue to protect your future?

Don’t.

Your practice can become more profitable, and you can focus on being a physician again.

CCPHP works to empower and protect the physician-patient relationship through a concierge medicine model, helping physicians practice the way they intended, and patients to receive the care they deserve.

To learn more about the innovative CCPHP approach, please call (212) 367-1950, or visit www.ccphp.net.

Is Concierge right for you?
Scan this code to find out!
What my practice was like before concierge medicine

I’m a family physician and we have a very busy primary care practice in Pasadena. We see patients of all ages from babies to seniors, and everybody in between.

Why I decided to explore concierge medicine

I wasn’t really looking to transition. I wasn’t even thinking about concierge medicine. But a friend had introduced me to a friend who was doing concierge medicine in Pasadena. A few years ago, there was a movement toward concierge medicine. But I didn’t really give it much thought because the only option we had seen at that time was to go fully concierge. And I didn’t want to do that.

And so when my friend introduced me to another friend who was doing this hybrid concierge model, I thought, “Oh, that’s interesting.” And then we got this flyer in the mail, and I thought, “Okay, I’ll take a look.”

I’m always interested in new things, and just out of curiosity I pursued it.

The benefits I’ve experienced from transitioning to concierge medicine

One of the things I’ve always wondered was: “What would it be like to have more time with my patients?”

This model is really nice, because we are able to spend an hour with our patients and I don’t feel rushed. And I think my patient doesn’t feel rushed. Now I see what it feels like to do that, and it’s really nice. So I feel like that’s a big benefit.

Sometimes in traditional practice you really felt kind of exhausted after a session because I was going from one patient to the next patient without having a lot of time to just regroup and think about that experience with our patient. This way you feel like you can process that information a bit more. And that’s what I really like.

The other thing I really like is that there’s an email that our patients can use that goes directly to my cell phone. So I get those emails very quickly, as opposed to logging into my EHR to get my emails through the patient portal.

I feel like it speeds up information coming from that patient, so it’s nice in that way, as well.

The biggest challenge I faced during my practice transition

Getting the logistics down. For example, we have a special phone line available for patients who are...
on this service. So when I’m seeing patients, my office manager or my nurse carry the phone with them, so that phone can be answered. Also, figuring out the schedule of where to put the time slots for our patients who are participating in this concierge program, so that we can honor all of the patient expectations and requirements. So just those logistics.

Otherwise, it was not difficult. It was a great transition.

If I could do the practice transition again, what would I do differently?

I didn’t go into it with a lot of expectations, but I feel like it went really well. I didn’t really know what to expect. So I was really surprised and happy about how many patients did opt to participate in the program. When you start a program like this, you just think: “Who’s going to sign up for that?” We already offer our patients quite a bit, do they really want to have these extra services? Do they feel like they need that?

And what I found was that there are many patients who have needs, and they feel like they could benefit from having more direct access. We have patients who have many health needs that need a quick response, and that’s helpful to them. And then we have patients who are very busy. Maybe they have small children, and they just aren’t able to bring all their children into a visit.

Just having the convenience of being able to quickly email or text, that’s helpful. I was surprised to learn how many folks felt like this would be helpful to them.

How concierge has affected my feelings of burnout, work-life balance and career satisfaction

“I’d always wanted to know what it felt like to spend time with a patient without having to think about the time.”

I’d always wanted to know what it felt like to spend time with a patient without having to think about the time. And it’s been what I would have thought medicine was supposed to be when I went into it so many years ago. My patients are such gracious people, and they’re very considerate of my time. So even though they are participating in this program, where they could potentially email at any time or call at any time, they’re very considerate. And it’s helped to make our relationship better.

I really feel that it is helpful to people who need extra time. And I think that’s really what this program brings.

Why I chose my concierge vendor

They’re very encouraging. And what Concierge Choice did was they reached out to our patients and notified them that there’s this additional service for those who need it or would like something like that. And then they had this meeting at a local hotel, where they invited patients to come in, and they gave a presentation about the nature of the program, what kind of benefits folks would get from it. And they asked me to say a few words, and helped anybody who was interested gain more information or sign up if they wanted to.

The nice thing was that they did not pressure my patients. That was something I definitely didn’t want. So I feel like they helped us run smoothly and helped us be able to do the administrative side of the program so that I could just see my patients and not have to worry about certain things that needed to be done.

They really helped to make everything run smoothly.

My advice for physicians considering concierge

Often, we physicians don’t realize the needs of some of our patients. And that’s something that I came to realize — that there was a certain segment of our patient population that actually embraced having that extra time with their provider and that extra access.

The practice of medicine is the same, we follow the same guidelines, there’s nothing different about the kind of care that our patients in this program get. I think the biggest thing is just having the time and the access. You might be surprised — there are patients in your population who would really embrace this.

And so, don’t necessarily discount it and don’t feel that people may not sign up for it, because they may be looking for that. I would say, give it a try. I think it’s a win-win situation.
Concierge sustained my practice during COVID-19

As the owner of one of the last remaining private primary care practices in the Raleigh area, I was no stranger to the business end of medicine. Maintaining a successful, secure practice while trying to deliver the kind of personalized medicine that is critical to good patient care was a challenge few private doctors in my area could sustain. Remaining in full control of my practice was important to me, and while I wanted to explore every option, I didn’t want to be reckless with a practice and patient base I spent years caring for and cultivating. Then I learned about Concierge Choice Physicians’ hybrid approach to membership medicine.

The Hybrid Choice model allowed me to venture into membership medicine at my own pace, with an optional program that patients could select. I continued to see all the patients in my practice, even those who didn’t join Hybrid Choice, and I didn’t have to make any structural changes. If the program didn’t work out or wasn’t well received, I hadn’t risked anything.

What happened next surprised me. My Hybrid Choice program was enthusiastically received by my patients and filled to capacity immediately. I had suspected my patients were as frustrated by the depersonalization of medicine as I was, but I hadn’t realized just how important it was for them to cement their relationship with me and to have peace of mind knowing the doctor they trust would be available to care for them whenever they needed.

Things went well, and after a year of managing both my traditional practice and my Hybrid Choice program, it became clear that concierge medicine was the right path forward for my practice and my patients. The patient demand was too great, and the program benefits too clear, to limit membership. I contacted Concierge Choice Physicians and they helped me to transition my practice entirely to a membership medicine model.

The ability to step into concierge medicine before making a full commitment was invaluable. As a private business owner, my patients and my reputation are my most important assets, and I needed to make sure this style of medicine would be successful. I felt reassured by the process and the ability to proceed at the pace and on the timeline that made sense for my practice, patients and staff, instead of being pressured from the start.

We couldn’t be happier with our decision. Especially through this COVID-19 health care crisis, my concierge practice has sustained us. Not only has it protected my practice from decreased patient visit revenue, it has given me the time to review all of the latest medical research and communicate personally with my patients. I wouldn’t have been able to do that in my traditional practice. I probably wouldn’t still be in business without my concierge program.

I encourage other doctors who are risk-averse but looking for ways to support their practice and their patients to consider the Hybrid Choice model by Concierge Choice Physicians. There are no upfront costs, and nothing needs to change within your practice, other than carving out a few concierge hours from your schedule. You continue to see all of your patients and maintain insurance and referral relationships. You get the revenue benefits of a concierge program without the risky practice overhaul. And, if it works for you, as it does for many physicians, you can move forward if and when the time is right for you. ∗

Octavian Belcea, M.D., is a family physician and owner of Wakefield Family Medicine in Raleigh, North Carolina.

“I PROBABLY WOULDN’T STILL BE IN BUSINESS WITHOUT MY CONCIERGE PROGRAM.”

Octavian Belcea, M.D.
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What my practice was like before concierge

I was probably seeing about 30 patients a day. We started at about 6:30 in the morning and saw patients until 6:30 or 7:00 at night. It started to affect both my own personal life and the personal life of my staff. And that was when I decided, after seven years in traditional practice, that I needed to make a change and do something different.

Why I decided to explore concierge medicine

I don’t even think I knew about concierge medicine at the time. I think a vendor actually called me and asked me to consider it. And as I began to explore that a little bit it seemed like a really great idea. I was doing some other education that was going to put me in a position to be able to take better care of patients, and I felt as though that would require more time with each patient. The structure of my practice at the time was not one that would allow me to do that.

The benefits I’ve experienced from transitioning to concierge medicine

I actually feel like my time spent is about the same, I feel like I don’t have a big difference in the amount of hours that I spend working. However, that’s partly because I now do a lot of things outside the office. I’m doing some teaching and speaking and other things that are medical in nature that I’ve been allowed to do, because I actually have the time to do them. Now I probably see six to eight patients a day, depending on the season. And I probably take eight or 10 phone calls a day.

Concierge has freed me up to pursue other things that I enjoy doing, such as teaching and speaking.

The biggest challenge I faced during my practice transition

There were lots of challenges. It was about three years from the first time someone ever mentioned to me the idea of concierge medicine until I actually made the decision. And I think that was a good decision time frame. For me, I think that was what I needed to be able to make that decision, because it was very difficult to let go of many of my patients.

Because I was in private practice, these were my patients who chose to come to me specifically. So these were all people who chose to jump on board with me, and I had built long term relationships with them. That was really difficult to do, to make that change, and to decide that I was going to have to let them go (if they did not join my concierge practice).

I think probably the thing that helped was allowing myself the freedom to realize that I wasn’t letting them go, but that they were making the choice. And that was a really helpful concept for me to realize. The hard part was to realize that they were making the choice and they were making the choice not to stay with you.

I was also worried that I would not see the same demographic of
people that I had seen before. And that really didn’t happen. I think my practice today is about the same demographic as the patients that I saw before. So you’ll be really surprised how many people actually choose to sign up that you would never have expected and how many people choose not to that you would have been sure were going to be part of your practice.

I also was surprised at how many new patients off the street came to the practice that were not from my original practice. I have probably half my practice, perhaps more, of new patients who came specifically looking for concierge care.

If I could do the practice transition again, what would I do differently?

Probably a couple of things. I would definitely say to every single patient, “I think this is a really good idea for you and me.”

Another thing — and I did this of my own accord and would definitely recommend it — is keeping track of the patients you think you want to scholarship (provide free service or discounts because of financial considerations) until the very end, because so many of them will figure out a way to pay for their care. Wait and then say, “I am actually going to keep you on with a scholarship, And here’s how we’re going to do it.”

How concierge has impacted my feelings of burnout, work-life balance and career satisfaction

I think one of the reasons why we get so burned out is because we get frustrated with day-after-day saying to patients, “You’ve got to change your diet,” and people don’t change their diet. But if you’re not sitting down with them, and have time to actually explain what that means in detail, they’re not going to do anything different.

Seeing patient outcomes improve is probably the best part. Actually seeing patients get better because you invest time in their outcome, and they’ll invest time in their outcome. So I feel like I’m seeing patients getting better than before, because I’m actually able to figure out what’s wrong with them, where before I just didn’t have the time to figure that out, to ask the questions to listen, to take the time to be present for them like I can now.

Why I chose my concierge vendor

We did a lot of research, and looked at several competitors and different models that were available.

For me, I really wanted to keep the nurse practitioners that I had they had already established several patient groups that they really liked and cared for. And I thought why would I let go of that opportunity to keep them? And so part of it was wanting to keep the extra patients to be able to be part of that. And also, I love having those providers and having a collaborative effort. And it was a little daunting to imagine being by myself, so it’s nice to have that collaboration with other providers who are thinking about medicine and thinking about how we can take better care of patients.

The other reason: financially, it really matters what the cost is going to be and what they’re going to do for you after the transition. And the first vendor that we interviewed, all the people that I spoke to said, “Well, they really haven’t done anything for us since we did the transition.” But everyone I interviewed with Cypress Membership Medicine before I did the transition, they all said, “Hey, we really think this is a great thing that they do. And here’s this other great thing they do.”

So it seemed like it was a continuous relationship. And that’s what kept me with them, when they helped me the same way.

My advice for physicians considering concierge

The thing that you will fear the most is: Are enough patients going to sign up? And then number two is you fear letting patients go. I had a mentor speak to me about this. And he said, “You know, think about how many of those patients, if you were to die today, how many would actually show up at your funeral?” And sometimes I think about it a lot more.

I can’t explain that enough, that it’s a totally different relationship than what I had before.”
How concierge medicine saved my life

Transitioning to concierge medicine probably saved my life. That is a dramatic thing to say, but I think it is true. I was in a traditional internal medicine practice owned by a large regional medical system. As is typical, they had rapidly growing administrative staff and salaries and an overabundance of managers. To pay for that, there was constant push to see more patients in less time, and there were cuts to our compensation despite the increased workload. All of this, coupled with a cumbersome electronic health record that mostly helped the system, was a recipe for disaster.

I was staying up late many nights, trying in vain to finish charts. I had no time for exercise and drank too much coffee. I had a syncopal episode at work from fatigue, was carried out of my office by ambulance to the local emergency department. The only response from management was a call from a midlevel manager asking if I would be back at work the next day. I was on my own.

In an unhealthy way, I worked harder to try to get things done. This did not work, but the push from above continued. As a senior physician in my practice, I felt it my responsibility to push back, both for providers and patients. I found myself learning the now obvious truth that an employed physician can suddenly become an unemployed physician. I was shown the door.

I already had begun looking into concierge medicine, including signing up for the Concierge Medicine Today conference. I left that conference partnered with Cypress Physicians to help me set up my new practice. After two months of intense work, along with my wife (a nurse practitioner), we opened our new concierge practice.

Whenever someone looks into concierge medicine, there is a worry: Will it be successful? We quickly found out that there were many former and new patients glad to join. They felt that the calmer pace, personal interactions and family friendly feel of the practice were what they needed. This collaborative relationship was a nice fit for them and for me. Previously, I was about five months out for scheduling physical exams. Now most can be scheduled in a week or two, and same day for most acute problems. My patients have my cell number, and I encourage them to call if needed.

Taking care of patients has become enjoyable again. When COVID-19 hit, we found that our personal relationship with the patients fit well with their unique needs. The smaller office also allowed us to care for them and protect ourselves in a safer, less-exposed environment.

Concierge medicine has allowed me to decrease my stress level from crushing and hopeless to busy but manageable. I have started exercising and sleeping again. I have lost 40 pounds and no longer eat antacids like candy. I am a happier person at home and at the office. My wife and I decided early that we could make this practice fit our family needs. We have a playroom for our children at the office. We make all of the decisions, our overhead is lower than before, and our office is nicer.

Changing to concierge medicine has given me a new lease on life, improved my health and brought back my love of medicine. An unsustainable level of stress and horrible health habits have been transformed, allowing me a better balance between work and home. My home life is now a part of my work life, benefiting me, my family and my patients. I am taking better care of my patients. I am not answering to a large corporate entity that does not seem to care about individual patients or providers. I hope to continue this type of practice for years to come.

“Changing to concierge medicine has given me a new lease on life, improved my health and brought back my love of medicine.”

Mitchell Huebner, M.D., is an internist practicing in Dallas, Texas.
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What my practice was like before concierge

My practice, in a nutshell, wasn’t physically or emotionally sustainable for me. I had a traditional busy practice with over 3,000 patients. And my day would start at four in the morning — back then we were all going to the hospital — and back to the office at 7:30 a.m. And from 7:30 a.m. until close, it was 25 to 30 patients, five days a week, in 15-minute slots. The best time of the day, back then, was the time I was spending with the patients. The worst part of the day was the avalanche of phone calls; they came all throughout the day. I just couldn’t keep up with it, and I had to take two hours of phone calls home with me every night. And I think that’s when I really started to become overwhelmed and emotionally unhappy.

Why I decided to explore concierge medicine

I didn’t think that the way I was practicing was best for the patients. I knew it wasn’t best for me physically and emotionally. More importantly, I knew it wasn’t right for the patients. I didn’t have enough time to read and to learn, to research things and to take deep dives into each individual person. And that’s really what I wanted to be able to do. I had to just treat diseases, my practice was all about sick care.

The benefits I’ve experienced from transitioning to concierge medicine

Back then, I was a mile wide and an inch deep. And now I’m a mile wide and a mile deep on every problem I go over with patients. So I think for me it was all about being able to spend more time with patients to do the job I knew I could do. This allows me to be the perfectionist that I am absolutely hardwired to be — it was very hard to leave a visit unfinished. And that just never happens now. So I’m able to be my perfectionist self. I’m able to do what I love, the way I love to do it. And the best part of my day is that work is my happy place. And I absolutely could not say that about my own practice before.

My day is structured like this: I do three of our annual wellness exams every day, each one lasts two hours. And those are just amazing visits, they’re sort of
It truly is amazing to not have that internal clock ticking away during these office visits.

**The biggest challenge I faced during my practice transition**

The hard thing was describing an idea to patients, and asking them to trust me that I was going to create something completely and totally different and amazing. I remember saying to patients, “Look, I this practice idea is going to help you live longer, it’s going to help you live healthier. And I really want you to be a part of this.” And I think when you say that to patients, patients really want to be with you. But it is hard to have a concept and to struggle a bit to describe that because you haven’t done it yet.

The transition is challenging, and that is the primary reason why I decided to go with a battle-tested, time-tested network like MDVIP. With them, there was a well-scripted and organized four months transition. It was hard, you take a day with 25 patients — because you’re not slowing that down — and add five minutes to every visit because you need to personally talk to patients about what you’re going to do. But it’s your job to do that and I felt it was incumbent on me to be the one that told my patients, “here’s what I’m doing, here’s why I’m doing it.”

**If I could do the practice transition again, what would I do differently?**

My transition went phenomenally. I did not make a mistake that a lot of other doctors make doing this transition, and that is profiling patients. I think there is a misconception out there that this type of medicine — whether you call it concierge or concierge style, which is the way I would describe my practice — isn’t for everyone. And I think a lot of doctors make the mistake, “I’m going to talk to this man or woman because he or she is a CEO or lawyer” or somebody who may have a big income, and they don’t talk to the policeman or the teacher or the house cleaner. I talked to everyone just the same.

**How concierge has affected my feelings of burnout, work-life balance and career satisfaction**

I was just upset, I was anxious. Some days I was just downright miserable, and I didn’t know how I would make it through the day. Now I can’t wait to get out of bed and get to work. And my day is paced, much less like a sprint, and much more like a slow jog. I’m able to really be a part of my patients’ lives and to really get to know them as people and souls. For the first 11 years, I was in traditional practice, and I missed everything in my life. I didn’t see my kids grow up, I missed all the school plays, the sports, my marriage, everything.

And now I miss nothing. I don’t have to cut any corners.

**Why I chose my concierge vendor**

I chose MDVIP because they were incredibly organized, incredibly well-scripted; they have a department for everything. There’s a legal department, regulatory department, EHR department and IT department. They have the transition department to help you go from your old practice to your new practice. They had a metrics calculator that told me this was going to work for me, and predicted with a high degree of accuracy how many patients I would have. Because that’s a big concern for a lot of doctors. If you’re going to make this change, you at least want to have a break-even on your salary.

I think too many doctors basically transition their practice alone, or with the help of an attorney they know, without the help of a big network. And they don’t open with the large numbers that MDVIP doctors open with, and they don’t have the help that they need.

**My advice for physicians considering concierge**

The most common comment from doctors who finish a transition in my network is “I wish I had done this sooner.” I think as doctors we’re all healthy skeptics, and we are all victims of our own paralysis by over-analysis. And you don’t want to do that.

I’m sure there are amazing doctors out there that are somehow able to create what I’m describing in a traditional setting. But, to me traditional internal medicine, even if you’re really good and you’re really busy, is like the standard American diet, and almost no one that eats that is healthy. And so if you can create this kind of practice for you, you should.”
‘You deserve to live’: Why I became a concierge physician

I came home late one night and told my wife Jennifer that I was just so far beyond exhausted. She looked me in the eye and didn’t miss a beat: “You deserve to live.”

Before I joined MDVIP, my life was hell. I was a solo practicing internist with a 15-year career and at 46, I was already burned out, fried, had no time with my family and friends or my hobbies, let alone time to stay up with the latest medical research beyond skimming headlines. Each day was a high-pressure, uphill battle of not enough time.

I was working 16-hour days, seeing 25 patients for a rushed 10 minutes from as early as 6 am just to get them in, and scheduled the whole day through until 7 or 8 pm — no break for lunch, no time for catch-up. I’d get home at 8 or 9 pm after putting out fires, looking at test results, and dealing with the increasing amount of paperwork that was drowning me, then working all day Saturday and half of Sunday just to try to keep on top of things.

I was mentally and physically depleted and constantly stressed.

I put on 30 pounds, felt lousy and had no quality of life.

Now that I’m an MDVIP-affiliated physician, there isn’t one part of my life that hasn’t improved. I have time with my family, I’m feeling healthier, I’m doing what I enjoy: hiking, cycling, cooking, and even got a guitar. And I spend on average at least half an hour with each patient.

I can fully practice preventive medicine and really address each patient’s underlying needs. I’m also making twice as much income from my practice with 20% the patient volume, thoughtfully seeing 10 to 12 patients a day and able to dedicate time to their needs and do research.

I have my wife and kids to thank in a big way. They said, “We need you. Something has to give.” They were right.

Before that moment, my gut response to fix things was to work harder, faster, and start earlier. But this time I took action the very next day and started my due diligence looking at my options. I explored selling my practice to one of three local hospital systems, and after meetings with them, received three offers. Then a physician friend who’d joined MDVIP said, “Look, you should check it out. It changed everything for me, and it could for you.”

Making the call to MDVIP was the best thing I’ve done for my practice, my family, my life — and my patients. It’s a big decision — I know. I was scared. But then I spent a weekend with the MDVIP executive team — at their invitation and on their dime — at a gathering of affiliates and other physicians considering joining the network to find out more about MDVIP.

Being able to maintain my autonomy while benefitting from MDVIP’s support resources convinced me that this style of practice and working with them — the company with the most experience — was my solution. I tore up the employment offers and within a week signed with MDVIP. I can honestly say it was one of the best decisions of my life.

It’s amazing to be able to give patients more time and to be more present for my family. In a nutshell, I got my life back and love being a doctor again.

David Maleh, M.D., is board certified in internal medicine physician in Wilmington, Delaware.

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What my practice was like before concierge

I had been in practice for almost 25 years. So I had a fairly big practice and about 2,500 patients, plus two nurse practitioners. So that would add on maybe another 700 patients, so very, very busy. I was in the hospital making rounds. We were doing about 1,200 occupational physicals a year. So our workday started at 6:30 in the morning, and oftentimes, I wasn’t home until 8, 9, or 10 o’clock at night.

Why I decided to explore concierge medicine

I think the biggest thing was burnout — I was tired of it — and the total work-life balance that I had. I struggled to be home with my wife and kids and to do what I wanted to do. It just wasn’t working anymore for me. I got very frustrated with the EHR. I was very frustrated with lots of other insurance issues that were going on. I had no time to study or to read. I have a master’s degree in public health and I really enjoyed teaching, and there was no way I could teach. I couldn’t do what I wanted to do.

So I was considering retirement; I was thinking “I don’t need this anymore. I’m done with this.” Then I heard about concierge medicine, and I decided to check this out. Our area was fairly new to concierge at the time. And so I wanted to give it an opportunity and see what maybe I could do, because I really wasn’t ready to retire. I didn’t want to retire but I was feeling pushed to do that.

The benefits I’ve experienced from transitioning to concierge medicine

I am so glad I did this. It changed the nature of my practice. Being in the concierge program, I have more time to be with my patients; I was able to go ahead and teach. People were motivated; they sign up for this program because they’re motivated to take care of themselves. I was able to enjoy my time at home more. And, of course, financially, it was an incredibly good decision for me.

In traditional medicine, 20 to 25 patients per day was not unusual at all. Now I have a limit of about 10 patients a day to complete physicals, which each lasts about an hour. And then I’ll spend anywhere from 20 minutes to 45 minutes, depending on the problem, with a particular patient and get things taken care of.
The biggest challenge I faced during my practice transition

The terrifying thought that I might not have anybody join me — that was the worst problem. I was very concerned about losing my base of patients. I mean, I could always go back and do something else and practice a different kind of medicine if I wanted to. But I think the scariest part was saying, “Are people going to be willing to make this plunge with you?”

Don’t forget, 10 years ago, concierge medicine was a lot more scary in terms of getting into the program than I think it is now, because people have accepted it as being a good quality program as medicine has fragmented even more. The need for a good quarterback, a primary care physician, somebody who’s going to have your interest is more important than it ever has been.

So I think the greatest fear was: Will I have enough patients?

If I could do the practice transition again, what would I do differently?

I would have done it sooner! I don’t think there’s anything different I would have done. The program that I was in was extremely good. Three months beforehand, they told all my patients about the program. We had a great opportunity to explain to patients why I was doing what I was doing.

I had a groundswell of support from the majority of my patients. And the attrition rate that I was so terrified was going to happen was much milder than I expected. I don’t think I would have done anything differently, other than be less anxious about the transition.

How concierge has affected my feelings of burnout, work-life balance and career satisfaction

It’s been dramatic. Over the years, I can tell you that my satisfaction level has gone up dramatically. I’ve been able to change my practice to a more holistic practice — that is what I wanted to do for years. I have a chiropractor in my office, we offer physical therapy, I have a naturopath, we have trainers, we have counselors. I’ve been able to gradually assimilate them because I have the time to do this, which is the important thing. And it has been so wonderful.

With regards to financial remuneration, I have no financial concerns, nothing to worry about from that standpoint.

And the beautiful part is the ability to teach and take time with my patients. I now have a minimum of 20 to 30 minutes, sometimes 45 minutes; I have several slots for that. I do home visits on Fridays, because I can and it’s not financially driven that much anymore, because I have that support.

Why I chose my concierge vendor

I interviewed a number of concierge programs. I ultimately selected SignatureMD, which is the company that I’m with now. And the reason I did it with them is because they allowed me to keep my nurse practitioners.

The biggest problem I had was I didn’t want to let go of my patients. I didn’t want to select 200 people and to the rest say, “Well, sorry.” With my nurse practitioners, I was able to still see my patients through them. They would come to me and say, “Hey, I have a problem.” So I never felt I lost contact with those people; that was the biggest thing for me.

My advice for physicians considering concierge

You need to vet the concierge program very carefully, because each one is a little bit different. They have different reimbursement models and programs and how you do things. So that is very important.

Secondly, you have to have confidence in yourself. I think you have to feel, “My patients and I have a very good relationship, and patients want to come with me into this new journey.” So the confidence aspect is important.

Just say to yourself, “Look, I’m going to have fun, I’m going to have more time and I’m going to take better care of my patients. I want to go and do other things. And that’s why I want to take this big step because what I have now is not working for me.”
Concierge medicine is not an all-or-nothing proposition

Before I transitioned to a concierge model nearly two years ago, I had spent the last 17 years serving the community of Santa Fe, New Mexico. I never said no to anybody. As a result, I ended up with an older, sicker patient panel and was making countless hospital and office visits. I was working harder than I could have imagined, but had little to show for it financially.

While I enjoyed working with my patients, the situation eventually became untenable. I had no time for myself and no work-life balance. There just weren’t enough hours in the day to provide the kind of care my patients needed and the attention my family deserved.

At first, I was reluctant to transition to concierge care, because I didn’t like the all-or-nothing approach of most concierge conversion partners. I wasn’t ready to give up my patients of 17 years and start from scratch again. Then I met with SignatureMD. Their segmented model was different. It allowed me to transition to concierge care for my patients who enrolled as members, while providing the option of keeping my nonmember patients.

With the help of SignatureMD, the conversion process turned out to be surprisingly easy. I simply explained to my patients that this new model is the way medicine should be — with longer visits and a doctor who isn’t constantly running late and who will be there for them nights and weekends. Everything went smoothly, and I was able to keep almost all of my patients.

For physicians considering a transition to concierge medicine, my advice is that, even though the financial rewards can be substantial, it’s not just about the money and the lifestyle. Those things are nice, but they don’t compare with how good it feels to do a better job. My professional life is so much more satisfying now. I’m making my patients feel better more quickly, and I’m no longer concerned about how to pay my bills.

In fact, the COVID-19 pandemic hit not long after I transitioned. Unlike many practices, I didn’t have to shut down. I had the financial flexibility and time to secure additional personal protective equipment, add ultraviolet lights and implement thermal image scanning at check-in. I was the first physician in the area with antigen and antibody testing. Even though these items were not reimbursable or reimbursement was unclear, I was able to dive right in and do what was right. Time and money were no longer issues.

The cost of concierge care shouldn’t be an issue for patients, either. They don’t have to be financially well-off. The annual fee is about the same as what most patients pay for their cable bill.

In my experience, concierge medicine is simply better medicine all around. I didn’t have to abandon my patients. I can do the right thing without worrying about costs, and I no longer feel pressured.

In fact, my only regret about making the concierge transition is that I waited too long to do it. Given what I know now, I’d have done it much sooner.

Josh Brown, M.D., is board certified in internal medicine and pediatrics. He practices in Santa Fe, New Mexico.
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BRADFORD S. PONTZ, M.D.
FAIRFAX, VIRGINIA

What my practice was like before concierge

We were successful and a very busy practice; I had worked for the group for about 14 years. We had been completely independent.

About five years before the concierge transition, we joined a medical group that was new and forming in our area. The medical group did offer some advantages financially — we were able to, through them, negotiate better reimbursement with some of our commercial payers. And we did do better overall financially with that group.

The challenge was that a lot of the newer contracts we were able to take advantage of through that group involved performance types of reimbursement models, with a need for lots of documentation of quality measures.

And it really did introduce a lot of burdens. It almost felt like I was not able to deliver the medical care that I was comfortable with.

Why I decided to explore concierge medicine

I had been familiar with concierge medicine for a number of years before we actually made the decision. I knew several physicians who had made the transition, including two who left the group that I worked with to establish their own solo concierge practices. At the time that those physicians did it, I felt they had been in practice in the area a bit longer than I had; they were older than I was. There was another physician in our group who was closer to my tenure, and I felt that he and I were just not quite ready.

But as time went on, and I saw the various challenges with the models I’ve described, it became clear to me that the concierge model really offered the best advantages.

The benefits I’ve experienced from transitioning to concierge medicine

The benefits are numerous. We have significantly fewer patients than we used to in the practice; I have about 25% to 30% of the patients that I used to have. So with a change of that magnitude, we are really able to spend a lot more time with our patients and just deliver a lot more for them. We can spend about twice as much time for each patient’s visit. It means we can be a lot more thorough with our care, we can address all the patient’s questions or complaints when they come in for a visit. And the pace of the visit is more relaxed.

We have more time to be available in other ways. The patients have my email address, and they my personal cell phone number. They can contact me if there’s something urgent comes up.
The biggest challenge I faced during my practice transition

The biggest challenge was wrestling with the fact that, by definition, there were some patients of mine who were going to be forced to move to another physician. And these were often patients who had been long-time patients of mine that I had enjoyed working with; we had a good relationship. And they would have been happy to stay with me except for this transition. And so I did have to make sure that I was comfortable with it.

But we took a lot of steps to mitigate any adverse effects. We worked with a large number of other practices in the area who were doing what we would call traditional practice. And we made sure that there were practices we knew and respected in the area that could absorb these patients. I spoke to those practices directly myself, and we created a list of best practices for the patients.

We did have the ability to enroll a small number of patients on what we call scholarship basis, which means the patients do not need to pay the annual membership fee. And we did that for a few particularly elderly or complicated patients where it would be a real unfortunate event if they would need to transition to another physician. The vast majority of the patients who chose not to move with us and enter the concierge model said, “I understand why you’re doing this and I wish you well.”

Interestingly, in the 2 1/2 years since our enrollment period, we have had a number of those patients come back to the practice.

“Our days are fulfilling, and we’re able to feel proud of the care we’re delivering.”

We were a bit short staffed during the transition period. It is a busy time, because you’re still trying to do all the medical topics of a visit, while also having a brief conversation about your concierge transition during each visit. If I had to do that over again, I probably would have just hired some temporary help for the transition, because it was a stressful period for the physicians and the support staff.

How concierge has affected my feelings of burnout, work-life balance and career satisfaction

I love being a physician, I love taking care of patients and knowing them over a period of time as their primary care doctor. It was just the high volume nature of the patient load and the need for chart documentation that was really taking time away from my personal life. I’m spending less time after hours doing chart work.

Because I used to be so busy seeing a large number of complicated patients each day, I wouldn’t get a chance to do all my charting during the day. It was really starting to create a personal life that was untenable. So I’m happy to have a bit more time for my family on evenings and weekends.

Why I chose my concierge vendor

I did a fairly thorough analysis of different concierge consulting companies about three years ago as we were preparing.

We chose Specialdocs Consultants, and, for us, they’ve been a great fit. They have a lot of experience in the field. They offer a lot of flexibility and seem to understand that every practice is different. And there is not a need for every practice’s transition period to be exactly the same and a certain protocol. Nor does every practice need to look and operate exactly the same on the far side of the transition. They are a small enough group that we’ve really had the opportunity to get to know them. We’ve been very happy with the experience.

My advice for physicians considering concierge

Don’t be afraid of the transition. I think there are a number of physicians out there who are understandable put off by some of the risks associated with it. But the rewards really are there.

One does need to do some type of analysis of the practice and make sure that you can support it economically. But I would encourage everyone to have confidence in their own practice and in their own relationship with their patients. There may be more interest among their patients than they initially realize.

Other concierge physicians have said what I’m about to say: One of my few regrets is that I didn’t make the transition earlier. I’m glad I’ve made it now.
Time well spent: Reflections on seven years as a concierge physician

When I made the change from a large, busy hospital-based primary care practice to a personalized care concierge model in 2013, the healthcare landscape was already starting to crumble under the weight of escalating demands. I experienced it every day, recognizing that patients who needed to see me couldn’t or saw a nurse practitioner instead. No matter how smart or efficient I was, it wasn’t possible to provide patients with any more than a cursory evaluation.

One case I still remember well: an elderly patient dealing with three different cancers slowly walked into my office 10 minutes late for a 15-minute appointment. Toward the end of this already too brief visit, his wife mentioned that he was also experiencing short-term memory loss. This, coupled with the complexity of his other conditions, made it impossible to conduct an appropriately thorough evaluation and I asked them to schedule another appointment. This patient was not an anomaly.

Launching a private membership practice proved to be an ideal solution. I had considered it for years, but as we all know, it’s so much easier to keep the status quo, no matter how unsatisfying.

Now I only regret not doing it sooner. Long hectic days and exhausted nights have been replaced by a manageable workload with a much smaller number of patients — every one of whom I know well — and time restored to spend with family and friends. I really feel like I got my life back.

The journey was gratifyingly devoid of unexpected drama or challenges, thanks to a supportive community and expert guidance from my consultant partner, Specialdocs. I am very good at medicine, but I am not a businessman, and freely admit I could not have done this myself. They provided a road map to follow which covered everything from meeting patient expectations to setting up a new office, and most importantly, gave me the confidence to know that my concierge practice would succeed.

It did from the start, and in the past six months, has gained more traction than ever in the face of COVID-19’s hard lessons about lack of available primary care in many communities. Even before that, patients were frustrated by an overcrowded, confusing health care system.

The pandemic also illuminated the irrereplaceable value of a one-to-one relationship with my patients. What stands out most to me is the universally positive feedback received from sending personal email updates on the situation to every patient in the practice. They’ve shared how incredibly grateful they are to receive information they can trust.

Recently we held two drive-through flu shot clinics, enabling patients to stay safely in their cars for this important preventive action. The response has been amazing, and I’m again reminded of the enormous privilege of being able to deliver care with no constraints on time or need to seek administrative approvals. The only meaningful measure is benefit to my patients.

My advice to physicians still hesitant: talk to other concierge doctors in your area and educate yourself on your options for a partner with expertise, experience and an outstanding reputation (in my opinion, Specialdocs has all three).

Think back to your initial hopes and dreams. As a primary care resident, I intended to guide patients through unrushed acute care and wellness visits, continue to care for them if they were hospitalized, and be proactive and thorough about disease prevention.

I am thankful to have restored my original passion for medicine. Don’t settle for anything less than being able to run your practice exactly the way you want. 

“I REALLY FEEL LIKE I GOT MY LIFE BACK.”

Daniel R Jasper, M.D., is an internal medicine physician in Creve Coeur, Missouri.

by Daniel R Jasper, M.D.
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What you must have in your employee handbook

Many health care businesses have an employee handbook, or employee policy handbook, but fail to update them on a regular basis. Here are some items you should be sure to include:

- **Social media** Do you have a social media policy? You can prohibit the use of social media in the work area on business time and on company computers.

- **At-will employment** If your state has an at-will employment law, you should also have a statement that the handbook cannot be considered a contract and that you have the right to make changes in an employee’s status whenever you feel necessary.

- **Disciplinary procedures** Do you have a policy that results in disciplinary action? You might want to review that process and delete the list. You might instead have a statement about honesty, ethics, respect and the attributes you expect from them.

- **Harassment** Do you have a policy that says harassment should be reported to the manager or supervisor? Just keep in mind that the manager/supervisor could be the person harassing the employee. You might want the employee to have the option of reporting to any manager. They need a way to report that does not affect their job in any way.

- **Benefits** Have you reviewed your benefits to make sure they comply with federal and state laws?

- **Leave and personal time off (PTO)** Does your handbook explain specifically how these will be calculated? Whether you choose vacation and sick leave in your business or PTO, you need to document how they will be calculated and when the employee will be eligible for these benefits.

Carol Gibbons, RN, B.S.N., NHA, is a health care business consultant. Send your legal questions to medec@mjlifesciences.com.
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Things You Should Know About Diagnosing and Treating Interstitial Lung Disease

Steven Nathan, MD
Medical Director, Advanced Lung Disease and Lung Transplant Program
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Falls Church, VA

This activity was written by PER® editorial staff under faculty guidance and review.

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When patients have interstitial lung disease (ILD), determining the precise type can pose a diagnostic challenge, given that ILD comprises more than 200 pulmonary disorders. Simply evaluating the patient for hypersensitivity pneumonitis (HP), one of the most common types of ILD, requires taking a history that covers a long list of environmental exposures. To make diagnosing and treating chronic fibrosing ILD more efficient in your practice, here are 3 important things you need to know.

1. Check for underlying connective tissue disease.

After idiopathic pulmonary fibrosis (IPF), connective tissue disease-associated ILD (CTD-ILD) is the second most common ILD diagnosis. Patients with ILD related to a connective tissue disease—such as rheumatoid arthritis, systemic sclerosis, Sjögren syndrome, polymyositis, dermatomyositis and systemic lupus erythematosus—may not have a previous CTD diagnosis. At least 15% of patients who present with ILD have signs or symptoms of underlying CTD, and the risk of CTD-ILD appears particularly high in female patients and those under the age of 50 years.

≥15% of Patients with ILD Have Evidence of a CTD

The American Thoracic Society/European Respiratory Society/Japanese Respiratory Society/Latin American Thoracic Association (ATS/ERS/JRS/ALAT) guidelines recommend serological testing for CTD in all patients with newly identified ILD of unknown cause who are suspected of having IPF. The guidelines do not recommend specific tests, but guideline panelists routinely test for antinuclear antibodies, rheumatoid factor and anti-cyclic citrullinated peptide. Additional testing may be necessary for suspected cases of specific CTDs, such as a myositis panel if antisynthetase syndrome is suspected, or anti–Scl-70, anticientromere and anti–RNA polymerase III in patients who may have systemic sclerosis (SSc).

2. Know the signs of ILD on high-resolution CT.

High-resolution computed tomography (HRCT) plays a central role in diagnosing ILDs, providing greater sensitivity in ILD detection and supporting earlier diagnosis than conventional chest radiography. Compared with conventional CT, HRCT amplifies the contrast between aerated lung and more solid components, emphasizing interlobular septa and small bronchi.

According to guidelines, a diagnosis of IPF requires—along with the exclusion of known causes of ILD—a usual interstitial pneumonia (UIP) pattern on HRCT, or in patients who have undergone biopsy, certain combinations of HRCT and histopathology patterns. The UIP pattern on HRCT includes the following:

- Subpleural reticulation with a basal predominance.
- Honeycombing (well-defined clustered cystic airspaces).
- Possible presence of peripheral traction bronchiectasis or bronchiolectasis.
- Absence of atypical features such as extensive ground-glass opacification.

“Sometimes the HRCT—which is the central diagnostic tool—in the context of the history and physical is sufficient to make a diagnosis.”
— Dr. Steven Nathan

In CTD-ILD, mixed UIP and nonspecific interstitial pneumonia (NSIP) patterns are common, as are unclassifiable patterns. Features that are useful in identifying chronic HP include infiltrates with a peribronchiolar and upper lung zone predilection; elements of groundglass, reticular and centrilobular opacities; variable amounts of fibrosis; and evidence of mosaic attenuation and air trapping.

3. Consider antifibrotics for appropriate patients.

In a 2015 clinical practice guideline for the treatment of IPF, the ATS/ERS/JRS/ALAT conditionally recommended the use of the antifibrotic therapies nintedanib and pirfenidone.

In vitro studies have shown that nintedanib reduces recruitment, proliferation and differentiation of fibroblasts and fibrocytes and decreases...
extracellular matrix deposition via inhibition of tyrosine kinase-mediated signaling. Pirfenidone has been shown to limit fibroblast proliferation and differentiation and collagen synthesis, though its mechanism of action is not well understood.

In the phase 3 INPULSIS trials for nintedanib, the annual rate of forced vital capacity (FVC) change was decreased in the nintedanib groups versus placebo (difference of 125.3 mL in INPULSIS 1 [P<.001] and 93.7 mL in INPULSIS-2 [P<.001]). Pooled data from the INPULSIS trials showed a trend toward a lower incidence rate of investigator-reported acute exacerbations in nintedanib groups versus placebo groups (5.3 vs 8.2 per 100 patient-years; risk ratio, 0.65; 95% CI, 0.40-1.04; P=.07). The most frequent adverse event with nintedanib treatment in both trials was diarrhea. Nintedanib has since been shown to slow the rate of loss of lung function in patients with SSc-associated ILD and patients with a progressive fibrotic phenotype.

Pooled data on pirfenidone from the CAPACITY and ASCEND trials showed that the risk of death from any cause or IPF at 1 year was significantly lower for the pirfenidone groups versus the placebo groups. Pooled data from these trials also demonstrated that patients treated with pirfenidone had a 48% lower risk of hospitalization for respiratory causes over 1 year compared with placebo-treated patients (P=.001). The most common adverse events with pirfenidone in CAPACITY and ASCEND were gastrointestinal- and skin-related, and dizziness was also common in CAPACITY.

However, neither treatment has been associated in large clinical trials with significant reductions in dyspnea or cough or improvement of IPF-related quality of life.

### APPROVED INDICATIONS

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<th>Nintedanib</th>
<th>Pirfenidone</th>
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<td>Treatment of IPF</td>
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<tr>
<td>Slowing rate of pulmonary function decline in SSc-ILD</td>
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<tr>
<td>Treatment of chronic fibrosing ILDs with progressive phenotype</td>
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IPF, idiopathic pulmonary fibrosis; ILD, interstitial lung disease; SSc-ILD, systemic sclerosis-associated interstitial lung disease.

Both antifibrotic therapies have warnings regarding elevated liver enzymes and liver injury, and these therapies are not recommended for patients with moderate or severe hepatic impairment.
CME POST-TEST QUESTIONS

1. Which of the following is most likely to enable early diagnosis of chronic fibrosing ILD?
   A. Routine chest X-ray
   B. Spirometry
   C. High-resolution computed tomography (HRCT)
   D. Fractional exhaled nitric oxide

2. Large clinical trials of antifibrotic ILD therapies have found improvements in all the following outcomes EXCEPT?
   A. Decreased change in forced vital capacity (FVC)
   B. Dyspnea
   C. IPF-related mortality
   D. Respiratory-related hospitalization

To learn more about this topic, including information on guidelines and recommendations for management of CF-ILD, go to gotoper.com/online-cme-activities/enduring-activity/enduring-ats20cfild.

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Things You Should Know About Eosinophilic Granulomatosis With Polyangiitis

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To learn more about this topic, including information on diagnosing and managing EGPA, go to gotoper.com/online-cme-activities/enduring-activity/enduring-ats20egpa

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:

• Discuss important diagnostic indicators for eosinophilic granulomatosis with polyangiitis (EGPA)
• Assess disease to develop an appropriate management plan for a patient with EGPA
• Develop a collaborative-care approach for patients with EGPA

Instructions for Participation/How to Receive Credit

1. Read this activity in its entirety.
2. Go to gotoper.com/go/polyangiitis2020print to access and complete the post-test.
3. Answer the evaluation questions.
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Eosinophilic granulomatosis with polyangiitis (EGPA), previously known as Churg-Strauss syndrome, is a rare eosinophilic vasculitis that occurs in patients with moderate to severe asthma. EGPA is a systemic disease with diverse clinical manifestations that complicate diagnosis and treatment. The pathophysiology of the disease remains poorly understood, but the prominence of allergic features suggests an immune-mediated disease mechanism.

The disease is rare; prevalence is approximately 18 per million people in the United States and ranges from 10.7 to 14 per million in Europe. Poor physician awareness hinders diagnosis. Mischaracterization of early-stage disease, which may be mistaken for severe asthma, can lead to misdiagnosis until the disease progresses to a more severe form. Here are 3 important things you need to know about EGPA in your practice:

1. **EGPA is difficult to diagnose.**

Between 91% and 100% of patients with EGPA have asthma, which is generally severe. Possible systemic symptoms of EGPA include fever, myalgias and weight loss. Organ involvement may manifest as ear, nose and throat; neurological; skin; gastrointestinal; cardiac; ophthalmological; or renal symptoms. Given this variability, an EGPA diagnosis can only be made after other eosinophilic diseases, infections, malignancies, drug reactions and rheumatologic conditions have been ruled out.

Three disease phases, each marked by distinct manifestations, have been identified: (1) the prodromal phase, which involves asthma and sinusitis or allergic rhinitis and can last up to a decade before progressing; (2) the eosinophilic phase, in which peripheral blood eosinophilia causes respiratory, gastrointestinal and/or cardiac symptoms; and (3) the vasculitic phase, which is marked by necrotizing vasculitis and granuloma formation. Patients typically progress slowly through these disease phases (over the course of years), but it is possible for the disease to rapidly progress over months. It is important to recognize that not all patients will progress through every stage at the same rate, some patients may skip stages and disease stages can overlap.

In the early stages of disease, particularly before the onset of vasculitic symptoms, EGPA can be difficult to distinguish from other eosinophilias such as granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). If EGPA is suspected, the minimum recommended work-up includes serologic testing for toxocariasis and human immunodeficiency virus; specific IgE and IgG dosages for *Aspergillus* species; search for *Aspergillus* species in sputum and/or bronchoalveolar lavage fluid; tryptase and vitamin B-12 levels; peripheral blood smear (looking for dysplastic eosinophils or blasts); and thoracic computed tomography scan.

Guidelines from the American College of Rheumatology state that a diagnosis of EGPA can be made in the presence of asthma plus eosinophilia with leucocyte count greater than 1.0 x 10⁹/L, plus at least 2 additional criteria:

<table>
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<tr>
<th>CRITERIA FOR DIAGNOSING EGPA</th>
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<tr>
<td>BOTH of the following:</td>
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<tr>
<td>Asthma</td>
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<tr>
<td>History of wheezing or diffuse high-pitched rales on expiration</td>
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<tr>
<td>Eosinophilia</td>
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<tr>
<td>Eosinophilia &gt; 10% of white blood cell differential count</td>
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<td>AND at least 2 of the following:</td>
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<tr>
<td>Extravascular eosinophils</td>
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<tr>
<td>Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatous inflammation</td>
</tr>
<tr>
<td>Mono- or polyneuropathy</td>
</tr>
<tr>
<td>Development of mononeuropathy, multiple mononeuropathies or polyneuropathy attributable to vasculitis</td>
</tr>
<tr>
<td>Nonfixed pulmonary infiltrates</td>
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<tr>
<td>Migratory or transitory pulmonary infiltrates on radiographs attributable to systemic vasculitis</td>
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<tr>
<td>Sino-nasal abnormalities</td>
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<tr>
<td>History of acute or chronic paranasal sinus pain or tenderness or radiographic opacification of the paranasal sinuses</td>
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<tr>
<td>Cardiomyopathy</td>
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<tr>
<td>Cardiomyopathy established by echocardiogram or cardiac MRI</td>
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<tr>
<td>Glomerulonephritis</td>
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<tr>
<td>Hematuria, red-cell casts, proteinuria</td>
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<tr>
<td>Alveolar hemorrhage</td>
</tr>
<tr>
<td>Identified by bronchoalveolar lavage</td>
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<tr>
<td>Presence of skin manifestations</td>
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<tr>
<td>Palpable purpura, skin nodules, urticaria, livedo reticularis, etc.</td>
</tr>
<tr>
<td>Anti-neutrophil cytoplasmic antibodies (ANCA)</td>
</tr>
<tr>
<td>ANCA-positive by immunofluorescence and perinuclear fluorescent ELISA pattern; may be myeloperoxidase positive or proteinase 3 positive</td>
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Targeted therapy can lower the steroid dose required to control symptoms.

In the acute setting, disease control takes priority; patients with life- or organ-threatening disease manifestations are treated with glucocorticoids, with or without immunosuppressants.\(^1,5,6\) Emerging treatments aim to limit long-term steroid use.\(^1,5\) Mepolizumab, a monoclonal antibody that targets interleukin-5 (IL-5), is the only FDA-approved targeted agent for patients with EGPA.\(^1\) Although generally safe in the majority of patients, the most frequent serious adverse events reported for mepolizumab are exacerbation or worsening of asthma.\(^9\)

The most common adverse events include headache, nasopharyngitis, arthralgia, sinusitis and upper respiratory tract infection.\(^9\)

New/Emerging Treatments for EGPA

- Mepolizumab
- Benralizumab
- Reslizumab
- Rituximab

Ongoing phase 2 studies are evaluating the efficacy of benralizumab and reslizumab, other IL-5 targeting antibodies.\(^10,11\) Rituximab, an antibody that targets CD20, is also being explored for EGPA treatment.\(^10,11\) Other agents that may be beneficial to select patients include intravenous immunoglobulins, interferon-alpha and leukotriene-receptor agonists, though additional research is needed to determine their roles in treating EGPA.\(^1,5\)

As a multisystem disease, coordinating medical care across specialties is vital.

Ultimately, the treatment of EGPA should consider each patient’s unique disease characteristics.\(^1,2\)

Shared decision-making is a key component of optimized patient care and is recommended for patients with ANCA-associated vasculitis.\(^1\) Educational programs are also recommended, as they can improve patients’ understanding of their disease and support improved outcomes.\(^1,14\)

Patients with EGPA may present to a variety of specialists; it is important for physicians to be aware of EGPA in order to recognize the disease in their patients. As EGPA is a rare disease with a broad range of manifestations and clinical characteristics, physicians should manage EGPA treatment in collaboration with other clinicians who have EGPA expertise.\(^1\) Indeed, a retrospective study that followed patients with EGPA over 20 years found that those receiving expert disease management had increased life expectancy and lower disease severity.\(^1,5\)

Clinicians who treat patients with EGPA should collaborate with specialists to optimize management of disease manifestations that affect specific organs.\(^1,2\) Patients with variable symptoms can benefit from a multidisciplinary team, as pulmonologists, rheumatologists, neurologists, cardiologists and gastroenterologists all may play a role in treatment. It is important to recognize when patients may benefit from specialist input.

KEY REFERENCES


For a full list of references go to: gotoper.com/go/polyangiitis2020print
1. In addition to asthma, which of the following is an early and important diagnostic indicator of eosinophilic granulomatosis with polyangiitis (EGPA)?
   A. Low-grade fever
   B. Severe pulmonary infiltrates
   C. Peripheral blood eosinophilia > 10%
   D. Reduced diffusing capacity of lung for carbon monoxide (DLCO)

2. A 38-year-old woman with a previous diagnosis of childhood asthma is experiencing worsening cough, dyspnea and upper-airway symptoms that have not responded to standard asthma medications or antibiotics. Several courses of high-dose corticosteroids have been required to control her asthma exacerbations. Her PCP refers her to a pulmonologist who lives in a city 2 hours away from her hometown. The pulmonologist orders bloodwork, chest computed tomography and pulmonary function testing. Results of the bloodwork lead the pulmonologist to suspect a diagnosis of EGPA.

   What is the most appropriate next step in managing this patient?
   A. Recommend bronchoalveolar lavage to confirm diagnosis
   B. Prescribe second-line asthma therapies to control exacerbations and have patient follow up with her PCP
   C. Refer patient to a physician who specializes in the management of systemic vasculitis and schedule follow-up with the pulmonologist
   D. Prescribe another course of high-dose corticosteroid with taper and provide patient with information on EGPA to help her recognize disease flares early

3. The patient in the prior question sees a specialist who confirms the diagnosis of EGPA. Which of the following is FDA-approved to lower corticosteroid dose in people with EGPA?
   A. Benralizumab
   B. Mepolizumab
   C. Reslizumab
   D. Rituximab

To learn more about this topic, including information on diagnosing and managing EGPA, go to gotoper.com/online-cme-activities/enduring-activity/enduring-ats20egpa
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### Contact Information

**Joanna Shippoli**

(440) 891-2615

jshippoli@mjlifesciences.com

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ANS TESTING

2. Can be combined with SUDOMOTOR into 1 full system
3. Takes less than 10 minutes to perform, software provides verbal cues
4. Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
5. Reimburses $170/test using 3 CPT codes
6. Provides a 1 page summary up to a full 24 page comprehensive report

SUDOMOTOR TESTING

3. Can be combined with ANS into 1 full system
4. Takes 3 minutes to analyze a patient’s hands and feet
5. Provides a 1 page summary report
6. Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
7. Reimburses $130/test (national average)

ALLERGY TESTING

4. Turn Key, comprehensive system
5. 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
6. 2 Minutes to apply, 15 minutes to show results
7. Reimburses average $270 - $350/test, cost is $100/test (antigens/applicators)
8. Options for Immunotherapy Treatment

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jshippoli@mjhlifesciences.com
SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

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

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe anaphylactic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days* of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older† (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Event</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHINGRIX %</td>
<td>Placebo%</td>
<td>SHINGRIX %</td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>12.8</td>
<td>3.4</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
</tr>
<tr>
<td>General Adverse Events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
</tr>
<tr>
<td>Myalgia, Grade 3*</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
</tr>
<tr>
<td>Fatigue, Grade 3*</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
</tr>
<tr>
<td>Headache, Grade 3*</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
</tr>
<tr>
<td>Shivering, Grade 3*</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
</tr>
<tr>
<td>Fever, Grade 3*</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>GI*</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
</tr>
<tr>
<td>GI, Grade 3*</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).  
* 7 days included day of vaccination and the subsequent 6 days.  
† Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.  
+ Placebo was a saline solution.  
* Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.  
* Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.  
* Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.  
* GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years. The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days. There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. For 0.01% of subjects who received SHINGRIX and for 0.09% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk.

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)].

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F).

Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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SGXJRNA200015 August 2020

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PINPOINT
PATIENTS

THE CDC RECONS MAY HELP YOU IDENTIFY PATIENTS FOR VACCINATION

50

No matter how healthy they may feel, people aged ≥50 years are at risk for shingles.1-5 That’s why CDC recommends you vaccinate immunocompetent adults 50 years and older with SHINGRIX.6,*

The CDC Recommendations may help you identify patients for vaccination and establish protocols in your practice.

To read the full CDC Recommendations, visit us at RecoSHINGRIX.com

*ACIP recommendations adopted by CDC.
ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention.

Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)

Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)
• SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for SHINGRIX on the previous pages.


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