STOP LEAKING CASH

Three ways to fix the bad habits hurting your bottom line

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- The CDC recommends that **adults 19 years of age and older** receive a dose of Tdap, if they have not previously been vaccinated with Tdap.¹

- In a 2018 survey, it was reported that only **31.2% of adults ≥19 years of age** received Tdap vaccination during the preceding 10 years.²,†
  - 46.1% of adults ≥19 years of age received an influenza vaccination in the 2017-2018 season.²,†
  - 69.0% of adults ≥65 years of age have ever received a pneumococcal vaccination as of 2018.²,†

- Although pertussis infection in adults is usually less severe than in babies and young children, complications can still occur. In one study, 91% of adults with pertussis (N=79) experienced a cough for an average of 54 days, and 61% of adults with pertussis (N=203) missed an average of 10 days of work in another study.³,⁴

- Depending on the vaccine, 79% to 85% of adult patients indicated they were **likely to get vaccinated if recommended by their healthcare provider.⁵**

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CHAIRMAN’S LETTER

Stop leaking cash

It’s the end of the year, and time for self-reflection. If you’re a business owner, especially if you’re running a business as complicated as a medical practice, it’s always a good idea to step away from the hamster wheel and evaluate where you’ve been, and where you want to go.

But self-reflection isn’t enough. Thinking about the challenges to your practice and then doing nothing about them is the easy way out. Fixing the issues that are holding you back from better revenue and better patient care is taking the next step.

OK, so let’s say you want to confront your business challenges in 2022. What should you do first? How’s this: Stop leaking cash.

Every business is guilty. As long-time health care consultant David Zetter told us: “All businesses are leaking cash. There is money being lost in almost every single business, and medical practices are even more at risk because of a whole host of issues.”

The first step is knowing you have a problem (and even the best-run practices probably do). The second step is planning to deal with it. Our cover story is all about plugging that revenue leak, and we’ve identified three areas practices should focus on first. Check out the story on page 22.

The other content we’re proud of in this issue that will help your medical practice run better is part two of our 2021 Physician Bootcamp recap. The bootcamp was a live, two-day virtual event conducted in October, with nine educational sessions on various business aspects of being a physician today. We recapped the first day’s sessions in our November issue. Check out Day Two — featuring coding and documentation, revenue cycle management, remote patient monitoring, and wealth building — starting on page 25.

As always, we’d love to hear what you think of our content. Reach out at medec@mjhlifesciences.com.

Mike Hennessy Sr.
Chairman and Founder of MJH Life Sciences™
Three things you should know about managing alpha-1 antitrypsin deficiency

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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 features:

- 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

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Small company stocks appear poised for growth

By David S. Gilreath, CFP

After lagging large company stocks in recent years, small company stocks — currently the outsiders of the equity market — appear to be mustering to rise.

Various indicators seem to presage an ascent. The signals are perhaps most sanguine for small capitalization stocks in the value category — out-of-favor companies trading below their actual value, based on fundamental characteristics.

Being down makes small caps a more likely bet than large caps as time goes by, as the pendulum of investment inflows swings between opposing equity types.

After shooting up sharply in the fall of 2020, the Russell 2000 index was down less than many of these giants’ performance, the index was down less than many of its members.

The trend of weakening large-cap companies continued to the point where Morgan Stanley noted in October that “88% of S&P 500 members have experienced at least a 10% drawdown,” though on a “closing price basis, the index (had) only corrected by 5%.”

Meanwhile, there have been healthy stirrings from small caps, as represented by the S&P 600 index of small-cap stocks. As of August, this index’s one-year forward price-earnings ratio had been improving relative to that of the S&P 500.

This number was well under the 25-year average. This means that more than at any time in over a quarter century, investors have recently been getting more earnings in return for the prices they’re paying for small-cap stocks. They’re historically cheap relative to large caps, and more likely to rise. Along with these quantitative signals, small caps may have tailwinds from various economic trends:

- Most small companies are entirely domestic, so they stand to gain disproportionately from the rapid economic growth now underway as the nation continues to recover from the COVID-19-induced recession. These companies make stuff people are buying, and consumer confidence is currently strong. Contrary to suggestions of economic weakness, stemming from the current media obsession over supply chain disruption, economic growth is actually strong.
- Being exclusively domestically oriented has inherent advantages, as small companies are most likely to benefit from forces of reverse globalization. Some analysts see globalization as reversing to some extent, giving way to a new order of three basic economic zones that are more self-contained. This may lead to more isolated, less globally dependent business environments. Recent examples of reverse globalization include Ford Motor Company’s recent announcement of a $1.4 billion manufacturing facility in Kentucky (including an electric vehicle [EV] battery plant) and Intel Corp. breaking ground in Arizona on two microchip manufacturing plants costing $20 billion. This in a world where vehicles are often built in multiple countries: EV batteries are a global product (many are made in China), and microchip plants have typically been located in Asian countries.
- There’s increasing corporate and public support for this manufacturing repatriation amid concerns about China’s increasingly troubled economy.

Small-cap value stocks have a beneficial past. Historically, in the first two years of recovery from recession, value stocks have usually far outperformed growth stocks. Already, some stocks continued on page 7
Expenses continue to rise for physicians and hospitals

By Keith A. Reynolds
Associate Editor

As U.S. hospitals and physician groups attempt to bounce back from the latest surge of COVID-19, increasing expenses continue to hamper a full rebound.

In September, hospitals saw declines across most performance metrics and physician-group gains being offset by an uptick in investments needed to supplement physician revenue, according to consulting firm Kaufman Hall.

Both expenses and revenues continued to rise in September above those seen in the two years prior, but a 3.3% drop in outpatient revenue from August may signal consumer worries about accessing care in the most recent surge of COVID-19, according to the release.

“Multiple factors are contributing to alarming and sustained increases in hospital expenses,” said Erik Swanson, a senior vice president of data and analytics with Kaufman Hall.

When it comes to physician groups, they saw significant revenue and productivity gains in the second and third quarters, outpacing those seen in 2019 and 2020, but expenses rose past pre-pandemic levels for a third straight quarter. The increase was due in part to increases in nonlabor expenses like drugs and medical supplies. Due to this, the average investment/subsidy per physician full-time equivalent (FTE) increased to $231,654 in the third quarter of 2021, the release says.

Meanwhile physician productivity, measured as physician work relative value units per FTE, rose 9.4% compared with the same period in 2020, and net revenue per physician FTE jumped to $660,762, up 11.4% from the third quarter of 2020, according to the release.

“Physician activity has come roaring back in the second and third quarters of this year,” Matthew Bates, managing director and physician enterprise service line lead with Kaufman Hall, says in the release. “We’re seeing significant increases in physician productivity and revenue, but higher expenses are driving increases in physician investments.”

Kareo and PatientPop merge to focus on modernizing health care practices

By Todd Shryock
Managing Editor

Kareo, a cloud-based clinical and financial software company, and PatientPop, a practice growth technology company, announced the closing of their merger and unveiled the combined companies’ new name, Tebra.

The new company marries technologies from both companies, which currently support more than 100,000 health care providers, to modernize every step of the patient journey.

Tebra will leverage the expertise of the PatientPop and Kareo founders, executive teams and boards of directors. Dan Rodrigues, Kareo’s CEO, will serve as the CEO of Tebra. PatientPop co-CEOs and co-founders Luke Kervin and Travis Schneider will serve as Tebra’s chief innovation officer and chief corporate development officer, respectively. Tebra has formed a new executive team and board of directors comprised of executives and board members drawn from both PatientPop and Kareo.

Tebra has received $65 million in additional growth financing from Golub Capital to support the merger.

PatientPop and Kareo will continue to operate under their respective brands for now. With Tebra, joint customers will be able to use PatientPop and Kareo products.

STOCKS continued from page 6

small-cap value stocks are out-performing the broader category of small caps. Exchange-traded small-cap value funds, such as iShares Russell 2000 Value ETF (IWN) and Invesco S&P SmallCap Value with Momentum ETF (XSVM), have been running above the Russell 2000 small-cap index this fall.

If the various indications pointing to a near-term rise in small-cap stocks don’t prove prescient, many long-term investors who act on them moderately may be doing nothing more disadvantageous than adding much needed balance to portfolios that were probably lopsided with large-cap stocks. And those seeking small-cap exposure with downside protection might consider small-cap, options-based exchange-traded funds.

Thus diversified, these investors will be ready for the time when — not if — small caps rise. The pendulum always swings back.

David S. Gilreath, CFP, is a 40-year veteran of the financial services industry. He is a partner and chief investment officer of Sheaff Brock Investment Advisors LLC, a portfolio management company for individual investors, and Innovative Portfolios LLC, an institutional money management firm. Based in Indianapolis, the firms manage approximately $1.4 billion in assets nationwide.
COVID-19 and malpractice lawsuits: What the future may hold

by Bruce C. Shulan Contributing Author

Since COVID-19 arrived in the United States, health care providers have been working tirelessly to address every aspect of the pandemic. The public saw how frontline workers were making sacrifices day in and day out to keep as many people healthy as possible. But even as the media focused on this heroic work, behind the scenes COVID-19 was prompting significant changes to malpractice laws and regulations at the state and federal levels.

Providers should be aware of what has happened and of the changes that may occur in coming months and years.

Early pandemic

At medical malpractice insurer EmPRO, we have been keeping a close eye on the pandemic because global health events have the potential to expose both insured clients and insurers alike to staggering liabilities. Thankfully in New York state, where EmPRO is headquartered, the governor and the legislature moved swiftly to enact emergency measures that shielded health care professionals from the worst liabilities. Had they not done so, the pandemic had the potential to lead to the proposal of new, more stringent regulations and policies, which in turn could have resulted in increased premiums.

New York was hit incredibly hard with COVID-19 cases right from the start, with the first confirmed case on March 1, 2020. The legislature and the governor produced the Emergency Disaster Treatment Protection Act (EDTPA), which extended broad immunity to health care providers and facilities.

Around the state, hospitals filled with patients with COVID-19 had to bring in nurses from out of state, bring health care providers out of retirement, build temporary facilities to provide COVID-19 care and enlist doctors, nurses, physician assistants and others to provide services out of title — meaning outside their usual purview of care.

The EDTPA granted them immunity from liability in the diagnosis and treatment of patients with COVID-19, as well as other patients whose treatment was affected by a facility’s response to the pandemic. Before doctors knew precisely how to care for patients with COVID-19, many frontline health care providers had reasonable concerns that experimental treatments could not only expose them to the disease but also lawsuits. The EDTPA helped alleviate those fears.

Medical malpractice attorney Tom Benvenuto, J.D., of Benvenuto & Slattery says this was a critical decision that empowered health care providers to make every effort to save patients without fear of legal action. “The immunity the EDTPA provided to New York health care professionals was essential to the state’s response and handling of the pandemic because it enabled physicians to pursue necessary measures to care for patients that may have otherwise been construed as extraordinary under otherwise normal circumstances,” he said.

The federal government issued its own legislation on protections for frontline workers, facilities and
even personal protective equipment (PPE). The Public Readiness and Emergency Preparedness (PREP) Act provides liability immunity related to the manufacture, testing, development and — importantly for medical providers — use of medical countermeasures against pandemics and other public health emergencies. Essentially, the government extended liability protection to medical equipment and PPE manufacturers. With this protection in place, manufacturers such as General Motors, Ford, Fitbit and Procter & Gamble were able to quickly launch production lines or repurpose existing ones to make medical equipment such as respirators, ventilators, face shields and masks.

The PREP Act also covered health care facilities that were using these countermeasures. For example, in the event of a PPE shortage — as was seen across the country due to a global shortage — a facility may invoke the immunity from liability if a patient claimed that they contracted COVID-19 at that facility while the facility was reallocating what PPE they had available to them.

**In the trenches**

In the midst of the pandemic, medical malpractice insurers and the attorneys working with them began planning for a potential tidal wave of lawsuits related to COVID-19, given the potential for morbidity that the diagnosis carried for a significant portion of the population. This would have put a tremendous strain on insurers across the country.

However, the industry so far has seen relatively few cases. In fact, medical malpractice lawsuit filings were down during the pandemic. This was due, in part, to many states implementing a hiatus on filing lawsuits when lockdown restrictions began. Because there are statutes of limitations on filing cases, there may be more COVID-19-based lawsuit filings when those statutes approach their expiration dates. Plaintiffs may file cases in order to buy time hoping that there will be a change in how the courts interpret and apply the immunities. However, in many cases, this situation is still more than a year away.

**Returning to normal**

In August 2020, when New York’s infection rate was less than 1%, the legislature reduced the scope of the EDTPA to cover only patients with COVID-19, eliminating those tangentially affected by a facility’s COVID-19 care for others. Furthermore, the statute was repealed, thereby ending the immunity for providers treating patients with COVID-19 after April 6, 2021. New York has returned to business as usual for malpractice regulations. Although it has been amended a number of times, the federal PREP Act is still in place, and malpractice insurers, courts and health care professionals are paying close attention to any potential legal aftershocks.

According to Benvenuto, the industry must keep a close watch on how federal courts approach challenges to PREP Act immunities that may be filed. “Although the immunities appear to be ironclad, and cases would likely be dismissed by the court in light of same, any suit that survives an initial motion to dismiss could provide plaintiffs in each state a playbook to filing and maintaining a similar case,” he said.

In the end, the COVID-19 pandemic did not bring about a sea change in medical malpractice regulations or policies. States expanded immunities where and when they had to, and when conditions improved enough to remove those exemptions, it appears most states have gone back to what worked before. Fortunately, this means premiums have not seen a “COVID-19 spike,” but it remains to be seen if this will hold in the future, especially if the Delta variant or another variant proves lasting or if a new pandemic emerges. 

Bruce C. Shulan is president and CEO of EmPRO. For more than 30 years, he has served as a senior executive, board member, consultant and attorney to the insurance industry.
What you need to know about mentoring other doctors

by Heidi Moawad, M.D.

Being a mentor to other doctors is one of the responsibilities that you may hold at various points in your career. Most doctors have had one or more informal mentors, but few have had a prescribed or long-term mentor who has been a consistent guide for many years. There has been an increase in formal mentoring courses for physicians, and sometimes physician mentoring is structured as a systematized process. Many hospitals have adopted programs for physician mentorship, pairing up senior physicians with junior-level doctors. And professional physician coaches offer programs as well. If you are considering mentoring other physicians, it's helpful to clarify what type of guidance you intend to provide and to communicate your availability to your mentee, whether you are participating in a formal program or providing informal guidance.

Establish the type of mentoring

Physicians may look to mentors for a variety of needs. For example, you might have a skill set or you may have reached a position other doctors would like to achieve. It’s important to recognize your own strengths and to use these strengths to provide guidance in the area you are familiar with.

Defining the goals of the mentoring relationship can be useful to clarify expectations. If you will spend time guiding a medical student, resident or junior physician, you might be happy to do so casually as they navigate their new role. Or you might consider it worth the effort only if they will move forward to progress in a specific way. Knowing your own style will help you determine what type of mentoring you are capable of. And if goal setting is important to you as a mentor, then be clear about your expectations and provide the junior physician you are mentoring with next steps you expect them to take before your next meeting.

Frequency

Another important aspect of setting expectations involves the frequency of your meetings. With an informal mentoring process, you might not necessarily feel the need to provide a set structure. One drawback of this approach is that the physician you are mentoring might hesitate to contact you — or could end up contacting you more than you would like. Finding a common ground for the frequency and formality of your meetings can be helpful.

If you will be checking in and getting updates on their progress, it can be a good idea to schedule your next meeting and to agree on the frequency and intervals of your meetings. This can help you define your own responsibilities and help the junior physician understand what they should expect from you.

Duration

Mentoring another doctor can be a process that lasts for years, but sometimes it isn’t possible to continue mentoring someone after they have reached an advanced level in their career. You might not be equipped to guide someone beyond a particular goal post that is your niche. After they have reached a given point, you may become more of a peer than a mentor, and you may remain friends for the long term.

Make sure you are up to the task

Mentoring other physicians can feel flattering, but it’s best to acknowledge when you aren’t the right person to deliver what a potential mentee needs. If a young doctor looking to you for guidance is highly ambitious, it’s important that they aren’t under the impression that you are more successful than you actually are. And if a young doctor is looking for moral support, you might be able to provide that type of encouragement only if you are a deeply confident person yourself.

If you are feeling overwhelmed or intimidated in your job as a physician, consider whether it is the right time for you to take someone else under your wing. As they say on airplanes, put on your own oxygen mask before you help someone else with theirs. Sometimes bowing out of a responsibility that you can’t carry out is the most fair and honest thing to do.

Further reading

Singular financial planning for physicians

Your industry has changed.
Your practice has changed.
Shouldn’t your advice change too?

Ada Saper
Senior Vice President–Wealth Management
Senior Portfolio Manager
Wealth Advisor

Forbes Top Women Wealth Advisors, 2020, 2021

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Save money on taxes: 10 deductions physicians should check out

by Syed Nishat, BFA Contributing Author

With a turbulent 2021 drawing to a close, it may seem like the end of year is already here and there’s nothing left to be done for your finances. However, there are some tax planning strategies physicians can still put into action to set themselves up for solid tax savings for year 2021, especially when it comes to deductions.

Here are 10 deductions physicians should explore. Not every deduction is right for every physician, but you won’t know until you ask. It depends on each physician’s individual circumstances, so speak to your tax professional.

1 Claim qualified business income (QBI)
One important deduction we see people miss all the time, especially physicians, is something called the qualified business income (QBI) deduction. If you’re a self-employed physician, and let’s say you derive $100,000 from your practice as business income, you can write off 20% of this $100,000, or $20,000, as a deduction. A lot of times physicians say, “Hey, I don’t qualify; I’m a physician.” But if your income is below $315,000, you can qualify for the full QBI deduction, so please make sure you speak to your accountant or tax attorney about it.

2 Claim QBI in rental income
Second, there is also a QBI for rental income. Let’s say you have actively managed rental properties and you collect rent. You can write off 20% of the rent as a deduction as well. This is another one that physicians who own rental property miss all the time. The deduction equals 20% of rental income up to a maximum of 2.5% of unadjusted basis of depreciable property.

3 Accelerated depreciation
Third, in case you’ve purchased or you’re thinking about buying a vehicle before the end of the year,
2021 is a great year to do it. Accelerated depreciation, which Congress passed a few years ago, allows you to write off the full purchase of heavy SUVs, trucks and vans that weigh more than 6,000 pounds and are used for business purposes. Usually these big vehicles cost $50,000 to $70,000, and you can get the write-off for the full value of the vehicle by using accelerated depreciation.

4 **Food expense deduction**

The food expense deduction is another good one this year. When you buy food for your corporation, usually you can deduct only half the cost. This year, the deduction doubled, dollar per dollar, to almost 100%. I’m not suggesting that you have party every night at your corporation and spend lots of money on food, but speak to your CPA. This is most likely the last year you can get 100% write-off of food expenses for your corporation.

5 **Itemize when you can**

The standard deduction for 2021 is $12,550 for individual filers, $25,100 for married filers, and $18,800 for head of household filers. Instead of simply taking the standard deduction — most of the time when a physician sits down with a CPA they will do a standard deduction — you can do something called an itemized deduction. If you have itemized deductions — if you did home improvements this year, for example — those could be a part of an itemized deduction so you can go over the standard deduction the government has passed.

6 **Gift stock, not cash**

Many physicians probably bought stock this year that went up in value. And many physicians probably also do charitable donations. One of the mistakes we see is that they just give out cash as a donation. Now, if you have appreciated stock, the best way to donate is to give the appreciated stock as a donation. The beauty in doing it this way is you don’t pay any taxes on the gain, plus, you get the deduction as well. This is extremely beneficial. If you have a charitable trust and a donor fund, you can give the appreciated stock as a donation as well so you can get a bigger write-off.

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**“Not every deduction is right for every physician, but you won’t know until you ask.”**

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7 **SALT cap workaround**

We all have to pay federal taxes, but we have state taxes as well. For local property and state taxes, altogether, the maximum state and local tax (SALT) deduction is $10,000. It used to be if you pay property tax, you can write off all of it. But now the government has capped it at $10,000. Certain states, including New York and New Jersey, passed workaround laws that allow pass-through entities to pay the taxes through the corporation rather than individually. In that way, you can write off the full amount of the taxes paid. Speak to your CPA about that as it may apply depending on your circumstances and the state you live in.

8 **Opportunity zone investment**

If you were lucky enough to have a lot of financial gain this year, speak to your financial adviser and look into something called opportunity zone investment. It’s an area designated by a state as an economically distressed community where new investments, under certain conditions, may be eligible for preferential tax treatment. The good thing about investing in an opportunity zone is that as long as you hold the property for more than 10 years, there will be no capital gain taxes. This is a powerful financial tool that can be incorporated into your tax and overall financial planning as well.

9 **529 plan contributions**

In many states, residents can claim deductions for a certain amount for 529 plan contributions made during the year. This lowers state tax liability. As an example, a married couple filing jointly making contributions to a New York 529 plan may claim up to $10,000 per year as deductions when calculating New York taxable income. Contributions must be made by Dec. 31 to use this deduction in 2021.

10 **Tax harvesting to offset profit**

If you've been watching the S&P 500, you’ve likely observed that it is near a record year-to-date high. As a result, before the end of December, many actively managed funds will pay high taxable dividends and capital gains distributions. Tax-loss harvesting provides you the ability to minimize those gains and lower your tax liability by strategically selling securities, especially if they’re short term.

Syed Nishat, BFA, is a partner at Wall Street Alliance Group. He holds a bachelor's degree in business administration from University of Nevada, Reno. Syed holds the FINRA Series 7, FINRA Series 63 and FINRA Series 66 licenses, along with licenses for life, disability, and long-term care insurance. He also has been awarded the Behavioral Financial Advisor (BFA) designation.

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Select Important Safety Information

Flublok Quadrivalent and Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (including egg protein for Fluzone High-Dose Quadrivalent) or after previous dose of the respective vaccine. In addition, Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Don’t let influenza spread like wildfire.

Help contain it with better protection.

Flublok Quadrivalent and Fluzone High-Dose Quadrivalent are vaccines indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Flublok Quadrivalent is approved for use in persons 18 years of age and older. Fluzone High-Dose Quadrivalent is approved for use in persons 65 years of age and older.
Don’t let influenza spread like wildfire. Help contain it with better protection.

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Please see Brief Summary of Prescribing Information for Flublok Quadrivalent on the third spread, and for Fluzone High-Dose Quadrivalent please see the fourth spread.
Only 2 influenza vaccines have been proven to prevent more cases of influenza versus standard-dose vaccine comparators in older adults\textsuperscript{1–4}

**Fluzone\textsuperscript{®} High-Dose Quadrivalent (Influenza Vaccine)**

With 4-strain protection, Fluzone High-Dose Quadrivalent builds on the legacy of the trivalent formulation, which was proven to provide

\textbf{24\% BETTER PROTECTION AGAINST INFLUENZA} (95\% CI: 10–37)

Due to any lab-confirmed circulating strain compared with standard-dose Fluzone (Influenza Vaccine) in patients 65+.\textsuperscript{1,3}

Based on data from the trivalent formulation, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with the trivalent formulation compared with a standard-dose vaccine.\textsuperscript{1}

**Flublok\textsuperscript{®} Quadrivalent (Influenza Vaccine)**

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\textbf{30\% BETTER PROTECTION AGAINST INFLUENZA} (95\% CI: 10–47)

Due to any PCR\textsuperscript{a}-confirmed circulating strain versus a standard-dose quadrivalent inactivated influenza vaccine.\textsuperscript{2,4}

In this randomized controlled trial, the most common local and systemic adverse reactions to Flublok Quadrivalent included pain at the injection site, headache, and fatigue.\textsuperscript{2}

Learn more at sanofiflu.com
Important Safety Information for Flublok Quadrivalent and Fluzone High-Dose Quadrivalent

Flublok Quadrivalent and Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (including egg protein for Fluzone High-Dose Quadrivalent) or after previous dose of the respective vaccine. In addition, Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Flublok Quadrivalent and Fluzone High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks.

If Flublok Quadrivalent and Fluzone High-Dose Quadrivalent are administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be lower than expected.

Vaccination with Flublok Quadrivalent and Fluzone High-Dose Quadrivalent may not protect all recipients.

For Flublok Quadrivalent, in adults 18 through 49 years of age, the most common injection-site reactions were tenderness and pain; the most common solicited systemic adverse reactions were headache, fatigue, myalgia, and arthralgia. In adults 50 years of age and older, the most common injection-site reactions were tenderness and pain; the most common solicited systemic adverse reactions were headache, and fatigue.

For Fluzone High-Dose Quadrivalent, in adults 65 years of age and older, the most common injection-site reaction was pain; the most common solicited systemic adverse reactions were myalgia, headache, and malaise.

For Flublok Quadrivalent and Fluzone High-Dose Quadrivalent, other adverse reactions may occur.

Please see Brief Summary of Prescribing Information for Flublok Quadrivalent on the third spread, and for Fluzone High-Dose Quadrivalent please see the fourth spread.

To order Fluzone High-Dose Quadrivalent or Flublok Quadrivalent vaccine, go to VaccineShoppe.com® or call 1-800-VACCINE (1-800-822-2463).

Fluzone High-Dose Quadrivalent is manufactured and distributed by Sanofi Pasteur Inc.
Fluzone High-Dose Quadrivalent (CPT® code 90662) is a covered benefit under Medicare Part B.
Flublok Quadrivalent is manufactured by Protein Sciences Corporation, a Sanofi company, and distributed by Sanofi Pasteur Inc.
Flublok Quadrivalent (CPT code 90682) is a covered benefit under Medicare Part B.

Flublok® Quadrivalent (Influenza Vaccine), Sterile Solution for Intramuscular Injection

2020-2021 Formula

Brief Summary of Prescribing Information

1 INDIcATIONS AND USAGE
Flublok Quadrivalent is a vaccine indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Flublok Quadrivalent is approved for use in persons 16 years of age and older [see Clinical Studies (14) in the full prescribing information].

2 DOSAGE AND ADMINISTRATION
For intramuscular injection only.

2.1 Dosage
Administer Flublok Quadrivalent as a single 0.5 mL dose.

2.2 Administration
Invert the prefilled syringe containing Flublok Quadrivalent gently prior to affixing the appropriate size needle for intramuscular administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

The preferred site for injection is the deltoid muscle. Flublok Quadrivalent should not be mixed in the same syringe with any other vaccine.

4 CONTRAINDICATIONS
Flublok Quadrivalent is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine [see Postmarketing Experience (6.2) and Description (11) in the full prescribing information].

5 WARNINGS AND PRECAUTIONS
5.1 Managing Allergic Reactions
Adequate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.2 Guillain Barré Syndrome
The 1976 swine influenza vaccine was associated with an increased frequency of Guillain-Barré Syndrome (GBS). Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than one additional case per 1 million persons vaccinated. If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Flublok Quadrivalent should be based on careful consideration of the potential benefits and risks.

5.3 Altered Immune Responsiveness
If Flublok Quadrivalent is administered to immunocompromised individuals, including persons receiving immunosuppressive therapy, the immune response may be diminished.

5.4 Limitations of Vaccine Effectiveness
Vaccination with Flublok Quadrivalent may not protect all vaccine recipients.

6 ADVERSE REACTIONS
In adults 18 through 49 years of age, the most common (≥10%) injection-site reactions were tenderness (48%) and pain (37%); the most common (≥10%) solicited systemic adverse reactions were headache (20%), fatigue (17%), myalgia (13%), and arthralgia (10%) [see Clinical Trials Experience (6.1)]. In adults 50 years of age and older, the most common (≥10%) injection site reactions were tenderness (34%) and pain (19%); the most common (≥10%) solicited systemic adverse reactions were headache (13%) and fatigue (12%) [see Clinical Trials Experience (6.1)].

6.1 Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a vaccine cannot be directly compared to rates in the clinical studies of another vaccine and may not reflect the rates observed in clinical practice.

Flublok Quadrivalent
Flublok Quadrivalent has been administered to and safety data collected from 998 adults 18-49 years of age (Study 1) and 4328 adults 50 years of age and older (Study 2). In Studies 1 and 2, local (injection site) and systemic adverse reactions were solicited with the use of a memory aid for 7 days following vaccination; unsolicited adverse events were collected for ~28 days post-vaccination, and serious adverse events (SAEs) were collected for 6 months post-vaccination via clinic visit or remote contact.

Study 1 included 1330 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok Quadrivalent (n=998) or a comparator inactivated influenza vaccine (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) (n=332) [see Clinical Studies (14) in the full prescribing information]. The mean age of participants was 33.5 years. Overall, 65% of subjects were female, 59% white/Caucasian, 37% black/African American, 1.0% Native Hawaiian/Pacific Islander, 0.8% American Indian/Alaskan Native, 0.5% Asian, 1.4% other racial groups, and 16% of Hispanic/Latino ethnicity. Table 1 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or the comparator vaccine.

- Fever: Grade 1 (≤38.0°C) - 32%, Grade 2 (38.1°C to <38.5°C) - 7%, Grade 3 (≥38.5°C to <39.0°C) - 1%, Grade 4 (≥39.0°C) - 0%
- Headache: Grade 1 (≤40 mm) - 6%, Grade 2 (41 mm to ≤50 mm) - 39%, Grade 3 (≥51 mm) - 1%, Grade 4 (≥50 mm) - 0%
- Fatigue: Grade 1 (≤10 mm) - 7%, Grade 2 (11 mm to ≤20 mm) - 44%, Grade 3 (≥21 mm) - 1%, Grade 4 (≥20 mm) - 0%
- Nausea: Grade 1 (≤50 mm) - 10%, Grade 2 (51 mm to ≤100 mm) - 7%
- Myalgia: Grade 1 (≤50 mm) - 16%, Grade 2 (51 mm to ≤100 mm) - 7%
- Joint Pain: Grade 1 (≤50 mm) - 8%
- Injection-site Reactions: Grade 1 (≤10 mm) - 10%, Grade 2 (11 mm to ≤20 mm) - 4%
- Other Reactions:
  - Firmness / Swelling: Grade 1 (≤5 mm) - 7%, Grade 2 (6 mm to ≤10 mm) - 3%
  - Redness: Grade 1 (≤5 mm) - 9%, Grade 2 (6 mm to ≤10 mm) - 1%
  - Injection-site Reaction: Grade 1 (≤5 mm) - 10%, Grade 2 (6 mm to ≤10 mm) - 3%

Study 2 included 8672 subjects 50 years of age and older for safety analysis, randomized to receive Flublok Quadrivalent (n=4328) or Comparator (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) as an active control (n=4344) [see Clinical Studies (14) in the full prescribing information]. The mean age of participants was 62.7 years. Overall, 58% of subjects were female, 80% white/Caucasian, 18% black/African American, 0.9% American Indian/Alaskan Native, 0.4% Asian, 0.2% Native Hawaiian/Pacific Islander, 0.7% other racial groups, and 5% of Hispanic/Latino ethnicity. Table 2 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or Comparator.

- Fever: Grade 1 (≤38.0°C) - 20%, Grade 2 (38.1°C to <38.5°C) - 7%, Grade 3 (≥38.5°C to <39.0°C) - 1%, Grade 4 (≥39.0°C) - 0%
- Headache: Grade 1 (≤40 mm) - 5%, Grade 2 (41 mm to ≤50 mm) - 23%, Grade 3 (≥51 mm) - 1%, Grade 4 (≥50 mm) - 0%
- Fatigue: Grade 1 (≤10 mm) - 7%, Grade 2 (11 mm to ≤20 mm) - 44%, Grade 3 (≥21 mm) - 1%, Grade 4 (≥20 mm) - 0%
- Nausea: Grade 1 (≤50 mm) - 10%, Grade 2 (51 mm to ≤100 mm) - 7%
- Myalgia: Grade 1 (≤50 mm) - 16%, Grade 2 (51 mm to ≤100 mm) - 7%
- Joint Pain: Grade 1 (≤50 mm) - 8%
- Injection-site Reactions: Grade 1 (≤5 mm) - 10%, Grade 2 (6 mm to ≤10 mm) - 3%
- Other Reactions:
  - Firmness / Swelling: Grade 1 (≤5 mm) - 7%, Grade 2 (6 mm to ≤10 mm) - 3%
  - Redness: Grade 1 (≤5 mm) - 9%, Grade 2 (6 mm to ≤10 mm) - 1%
  - Injection-site Reaction: Grade 1 (≤5 mm) - 10%, Grade 2 (6 mm to ≤10 mm) - 3%

Table 1: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 18-49 Years of Age, Study 1 (Reactogenicity Populations) 1

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent (n=998)</th>
<th>Comparator (n=332)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with ≥1 injection site reaction 1</td>
<td>10%</td>
<td>6%</td>
</tr>
<tr>
<td>Local Tenderness</td>
<td>48%</td>
<td>37%</td>
</tr>
<tr>
<td>Local Pain</td>
<td>37%</td>
<td>36%</td>
</tr>
<tr>
<td>Firmness / Swelling</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Redness</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Subjects with ≥1 systemic reaction 2</td>
<td>34%</td>
<td>36%</td>
</tr>
<tr>
<td>Headache</td>
<td>20%</td>
<td>21%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>17%</td>
<td>17%</td>
</tr>
<tr>
<td>Muscle Pain</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>Joint Pain</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Shivering / Chills</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Fever 3</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 50 Years of Age and Older, Study 2 (Reactogenicity Populations) 1

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent (n=4328)</th>
<th>Comparator (n=4327)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with ≥1 injection site reaction 4</td>
<td>10%</td>
<td>7%</td>
</tr>
</tbody>
</table>

NOTE: Data based on the most severe response reported by subjects. Results ≥1% reported to nearest whole percent; results >0 but <1% reported as <1%.

*Comparator = U.S.-licensed comparator inactivated influenza vaccine manufactured by GlaxoSmithKline.

†Study 1 is registered as NCT02290509 under the National Clinical Trials registry.

‡Subjects with ≥1 injection-site reaction reported as any event.

§Subjects with ≥1 systemic event reported as any event.*


Study 4 included 602 subjects 50 through 64 years of age for safety analysis, randomized to receive Flublok (n=301) or another U.S.-licensed trivalent influenza vaccine (Fluzone, manufactured by Sanofi Pasteur, Inc.) as an active control (n=301).

Study 5 included 869 subjects aged 65 years and older for safety analysis, randomized to receive Flublok (n=436) or another U.S.-licensed trivalent influenza vaccine (Fluzone) as an active control (n=433).

Study 6 included 2627 subjects aged 50 years and older for safety analysis, randomized to receive Flublok (n=1314) or another U.S.-licensed trivalent influenza vaccine (Afluria, manufactured by Seqirus Pty Ltd.) as an active control (n=1313). Among subjects 50 through 64 years of age, 672 received Flublok and 665 received Afluria. Among subjects aged 65 years and older, 642 received Flublok and 648 received Afluria.

Study 7 was a Phase 2 dose-finding trial conducted in adults 18 through 49 years of age, 153 of whom received Flublok 135 mcg, the licensed trivalent formulation. Serious Adverse Events

Among 2497 adults aged 18-49 years of age (Studies 3 and 7 pooled), through 6 months post-vaccination, two deaths were reported, one in a Flublok recipient and one in a placebo recipient. Both deaths occurred more than 28 days following vaccination and neither was considered vaccine-related. SAEs were reported by 32 Flublok recipients and 35 placebo recipients. One SAE (pleuritis/pleuripenicarditis) in a Flublok recipient was assessed as possibly related to the vaccine.

Among 872 adults 50-64 years of age (Studies 4 and 6 pooled), through up to 6 months post-vaccination, no deaths occurred, and SAEs were reported by 10 subjects, 6 Flublok recipients and 4 Comparator recipients. One of the SAEs, vasovagal syncope following injection of Flublok, was considered related to administration of study vaccine.

Among 1078 adults 65 years of age and older (Studies 5 and 6 pooled), through up to 6 months post-vaccination, 4 deaths occurred, 2 in Flublok recipients and 2 in Comparator recipients. None were considered related to the study vaccines.

SAEs were reported by 80 subjects (37 Flublok recipients, 43 Comparator recipients). None were considered related to the study vaccines.

Among 1314 adults 50 years of age and older (Study 7) for whom the incidence of rash, urticaria, swelling, non-pitting edema, or other potential hypersensitivity reactions were actively solicited for 30 days following vaccination, a total of 2.4% of Flublok recipients and 1.6% of Comparator recipients reported such events over the 30 day follow-up period. A total of 1.3% and 0.9% of Flublok and Comparator recipients, respectively, reported these events in the 7 days following vaccination. Of these solicited events, rash was most frequently reported (Flublok 1.3%, Comparator 0.8%) over the 30 day follow-up period.

7. DRUG INTERACTIONS

Data evaluating the concomitant administration of Flublok Quadrivalent with other vaccines are not available.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure

Pregnancy outcomes in women who have been exposed to Flublok Quadrivalent during pregnancy are being monitored. Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Flublok Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive Flublok Quadrivalent during pregnancy in Sanofi Pasteur Inc.’s vaccination pregnancy registry by calling 1-800-822-2463.
Please continue reading to see Brief Summary of Prescribing Information for Fluzone High-Dose Quadrivalent (Influenza Vaccine).

Fluzone® High-Dose Quadrivalent  
Rx Only  
(Influenza Vaccine), Suspension, for intramuscular injection  
2020-2021 Formula

Fluzone® High-Dose Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine.

Fluzone High-Dose Quadrivalent is indicated for use in persons 65 years of age and older.

1 INDICATIONS AND USAGE
Fluzone® High-Dose Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine.

Fluzone High-Dose Quadrivalent should be administered as a single 0.7 mL injection by the intramuscular route in adults 65 years of age and older.

2 DOSAGE AND ADMINISTRATION
For intramuscular use only

2.1 Dose and Schedule
Fluzone High-Dose Quadrivalent should be administered as a single 0.7 mL injection by the intramuscular route in adults 65 years of age and older.

2.2 Administration
Inspect Fluzone High-Dose Quadrivalent visually for particulate matter and/or discoloration prior to administration. If either of these conditions exists the vaccine should not be administered.

Before administering a dose of vaccine, shake the prefilled syringe. The preferred site for intramuscular injection is the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.

Do not administer this product intravenously.

Fluzone High-Dose Quadrivalent should not be combined through reconstitution or mixed with any other vaccine.

4 CONTRAINDICATIONS
A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine [see Description (11) in the full prescribing information] including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration of Fluzone High-Dose Quadrivalent.

5 WARNINGS AND PRECAUTIONS
5.1 Guillain-Barré Syndrome
If Guillain-Barré syndrome (GBS) has occurred within 6 weeks following any previous influenza vaccination, the decision to give Fluzone High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated. GBS has also been temporally associated with influenza disease. (See references 1 and 2 in the full prescribing information.)

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Altered Immunocompetence
If Fluzone High-Dose Quadrivalent is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be lower than expected.

5.4 Limitations of Vaccine Effectiveness
Vaccination with Fluzone High-Dose Quadrivalent may not protect all recipients.

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice. One clinical study has evaluated the safety of Fluzone High-Dose Quadrivalent.

Study 1: (NCT03282240, see https://clinicaltrials.gov) was a randomized, active-controlled, modified double-blind pre-licensure trial conducted in the U.S. The study compared the safety and immunogenicity of Fluzone High-Dose Quadrivalent to those of Fluzone High-Dose (trivalent formulation). The safety analysis set included 1777 Fluzone High-Dose Quadrivalent recipients, 443 Fluzone High-Dose recipients, and 450 investigational Fluzone High-Dose containing the alternate B influenza strain recipients.

The most common reactions occurring after Fluzone High-Dose Quadrivalent administration were injection-site pain (41.3%), myalgia (22.7%), headache (14.4%), and malaise (13.2%). Onset usually occurred within the first 3 days after vaccination.

The majority of solicited reactions resolved within three days of vaccination. Table 1 displays solicited adverse reactions for Fluzone High-Dose Quadrivalent compared to Fluzone High-Dose reported within 7 days after vaccination and collected using standardized diary cards.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Fluzone High-Dose Quadrivalent</th>
<th>Fluzone High-Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>41.3%</td>
<td>41.3%</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>14.4%</td>
<td>14.6%</td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>41.3%</td>
<td>41.3%</td>
</tr>
<tr>
<td>Malaise</td>
<td>13.4%</td>
<td>13.4%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>22.7%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Ocular Hyperemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Summary of Prescribing Information

8.2 Lactation
Risk Summary
It is not known whether Flublok Quadrivalent is excreted in human milk. Data are not available to assess the effects of Flublok (trivalent formulation) or Flublok Quadrivalent on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Flublok Quadrivalent and any potential adverse effects on the breastfed child from Flublok Quadrivalent or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use
Data from a randomized, controlled trial demonstrated that children 6 months to less than 3 years of age had diminished hemagglutinin inhibition (HI) responses to Flublok (trivalent formulation) compared to a U.S.-licensed influenza vaccine approved for use in this population, strongly suggesting that Flublok (trivalent formulation) would not be effective in children younger than 3 years of age. Safety and effectiveness of Flublok Quadrivalent have not been established in children 3 years to less than 18 years of age.

8.5 Geriatric Use
Data from an efficacy study (Study 2), which included 1759 subjects ≥65 years and 525 subjects ≥75 years who received Flublok Quadrivalent, are insufficient to determine whether elderly subjects respond differently from younger subjects [see Clinical Trials Experience (6.1) and Clinical Studies (14) in the full prescribing information].

Manufactured by Protein Sciences Corporation (Meriden, CT).

U.S. license No. 1795.

Distributed by Sanofi Pasteur Inc.

Flublok is a registered trademark of Protein Sciences Corporation.

INFB4-BPLR-SL-JUL20

Revised: July 2020
6.2 Postmarketing Experience

Based on data from Fluzone High-Dose, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with Fluzone High-Dose compared to a standard-dose vaccine. Unsolicited non-serious adverse events were reported in 279 (15.7%) recipients in the Fluzone High-Dose Quadrivalent group and 140 (15.7%) recipients in the Fluzone High-Dose group. The most commonly reported unsolicited adverse event was cough. Within 180 days post-vaccination, 80 (4.5%) Fluzone High-Dose Quadrivalent recipients and 48 (5.4%) Fluzone High-Dose recipients experienced a serious adverse event (SAE). None of the SAEs were assessed as related to the study vaccines.

6.2 Postmarketing Experience

The following additional adverse events have been spontaneously reported during the postmarketing use of Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent and may occur in people receiving Fluzone High-Dose Quadrivalent. Because these events 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 vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent.

- Blood and Lymphatic System Disorders: Thrombocytopenia, lymphadenopathy
- Immune System Disorders: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- Eye Disorders: Ocular hyperemia
- Nervous System Disorders: Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including aseptic meningitis and transverse myelitis), facial palsy (Bell’s palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paresthesia
- Vascular Disorders: Vasculitis, vasodilatation
- Respiratory, Thoracic and Mediastinal Disorders: Dyspnea, cough, wheezing, throat tightness, oropharyngeal pain, and rhinorrhea
- Gastrointestinal Disorders: Vomiting
- Skin and Subcutaneous Tissue Disorders: Stevens-Johnson syndrome
- General Disorders and Administration Site Conditions: pruritus, asthenia/ fatigue, chest pain, chills
Addressing Influenza IN THE COVID-19 ERA

Interseasonal levels of influenza have fallen to historic lows. Some patients are now complacent about health risks from an infection. Others, in the wake of the COVID-19 pandemic, have vaccination burnout.

In this Medical Economics® Around the Practice series, Tina Tan, MD; John J Russell, MD; Stephan Foster, MD; and Charles Vega, MD; discuss how to educate patients on the importance of influenza vaccines, consider the lasting impacts of COVID-19, and examine case scenarios reflecting challenges physicians are likely to face this season.

Watch Now
Competition is increasing, and reimbursements are decreasing. Every dollar counts for most medical practices, yet many physicians have fallen into bad business habits that are costing them money.

Patients and payers have changed their payment expectations, but practices often lag behind, relying on outdated systems and processes to collect money. Budgets lack essential details needed for planning, leading to cash crunches at inopportune times, and safety nets like a line of credit either don’t exist or are inadequate.

“All businesses are leaking cash,” says David Zetter, founder and president of Zetter HealthCare Management Consultants. “There is money being lost in almost every single business, and medical practices are even more at risk because of a whole host of issues.”

Stop Leaking Money

Improve your practice’s cash flow with the right financial strategies

by Todd Shryock Managing Editor
When you can’t explain a variance as to why you deposited $43,000 — yet your billing report says you had $60,000 — either every penny needs to be explained or that is telling you that you have problems and need to figure out where the discrepancies are.”

Practices can minimize their leakage and maximize cash flow by setting up detailed financial systems, understanding their payer contracts and managing costs.

Create a solid financial system
The first step to improving a practice’s cash flow is making sure a system exists to track and manage it.

“I think the No. 1 mistake that I’ve seen is people just not actually having a cash flow management system at all,” says Akash Madiah, chief financial officer of the Medical Group Management Association. “And when I say system, it’s the process around it and understanding what the future cash flow needs are going to be for the practice. It all starts with the budgeting process.”

Practices need a thorough understanding of what’s going to happen in the practice in the next year, including when people get paid, whether it’s salary or bonuses and if investments in medical equipment are needed, as well as all the regular costs that need to be accounted for.

“It’s different from a P&L forecast because it’s the actual cash you need out the door that you’re going to need to make,” says Madiah. The forecast needs to also consider expected patient volumes. “Are you going to have a lot more patient visits during flu season? It’s just understanding all those nuances of your practice that is really key for any kind of forecasting ability.”

The system needs to also include a commitment to communicating with patients what their financial responsibilities are before the appointment and then collecting the money due while they are in the office.

“What you have to do is let the patient know upfront — and we advocate for two days out — that they pay not only the copay” but also “whatever their coinsurance may be” by doing an estimate when you verify the insurance, says Derick D. Perkins, a managing partner at Metis Advisors LLC. “And more important than that, you also set up the outstanding balances from previous visits.”

Most offices send letters about balances due to patients but don’t always realize that same patient might be coming in for a visit that week. “That’s your opportunity to set them up on a realistic payment plan,” Perkins adds. “One of the things that most organizations do not do well is they don’t have a firm policy and standards on how to set the plan up for the front office staff.”

To make sure patients can pay the practice, offer financing options. More patients are relying on high-deductible plans, putting more of the burden for payment on them rather than a payer. There are third-party organizations that work with doctors to help patients pay their bills. Patients with financial challenges may rack up thousands of dollars in care, making it unrealistic to pay the practice $25 a month for decades. Instead, they can finance it, and the office collects 85%-90% of the money upfront.

A good cash flow system should also focus on collecting money that’s past due. Perkins says to be careful not to focus exclusively on the largest bills when trying to collect. “Sometimes you never get down to the lower dollar balances,” he says. “Sometimes they can be $100, sometimes it can be $50, but those are the ones that are the most collectible in terms of monthly or one-time payments.”

In some cases, Perkins says it might be more expedient to offer a patient a settlement with a 15%-20% discount just to get cash into the practice rather than spending
“All businesses are leaking cash. There is money being lost in almost every single business, and medical practices are even more at risk because of a whole host of issues.”

David Zetter, president, Zetter HealthCare Management Consultants

months trying to collect the full amount. It’s not usually hard to figure out who to offer the deal to.

“You can see the difference in the ones who really care about their credit or the ones that typically want to pay their bills because they are going to offer you something,” says Perkins. “They will take advantage of it and pay something versus the one who is never going to pay. You can see balances in the system from previous visits, and that’s why it’s so important to try to collect as much as you can upfront when they first come in because when that person hasn’t paid their previous balance, the chances of them paying even with the discount are pretty slim.”

Understand contracts

Practices need to spend time understanding their payer contracts because the reimbursements are where the revenue cycle starts. Having copies of the contracts with reimbursement rates allows practices to project revenue based on past patient volume and current procedural terminology codes and to double-check that actual reimbursements match with the contracted rates.

Perkins says practices should track key metrics for each payer. For example, if certain procedures are being denied but then paid on appeal 90% of the time, that’s something that can be discussed at the next negotiation. Eliminating denials will boost cash flow by speeding reimbursement from the payer and freeing staff time for other activities.

Knowing the data can also boost a practice’s future reimbursement rate. “Not everyone can really negotiate in certain markets — what you get offered from certain payers is what you are going to get — but you have to have the analytics,” says Perkins. “When you sit down to let them know you want to get paid this amount, at least have the numbers available. Analytics is the key going forward because it reveals a lot more about what’s going on in your accounts receivable and what you are trying to get to.”

With detailed reporting, instead of looking at data on a 30- or 60-day lag, trends can be identified that might show a dramatic drop-off midmonth from a particular payer, buying time to reallocate resources to focus on another payer or making other financial moves, says Perkins.

In addition to payers, track vendors for their efficiency and how they affect your cash flow. For example, many practices use a vendor for collections but don’t always pay much attention to its performance. Perkins suggests using a second placement for debts the first agency didn’t collect on — to not just collect as much money as possible but also to measure the effectiveness of the first agency.

“If the second agency can pick up a good percentage, that means your first agency is probably not doing a good job collecting,” says Perkins.

Manage costs

The quickest way to boost cash flow is to cut costs, but for medical practices, most costs are usually labor.

Madiah says practices need to understand the costs of physicians, nurses and office staff and be willing to make adjustments based on forecasts. “It really starts with understanding your volume that’s coming in the door,” he says. “When you know your volume, you know the right staffing levels to have.”

A common mistake is having the same staffing all year when volume is cyclical. In the down months, hours should be reduced.

Whether to lease or buy equipment is another consideration. Leasing might appear to cost a practice more over the life of the machine, but certain variables need taken into account. “Is this equipment something that’s going to need a lot of maintenance over the years? If so, leasing is always a good option because someone else will take care of that,” says Madiah. “If you buy it, it’s yours, and you have to commit the time and money to fixing it.”

Likewise, buying an office space for the practice instead of leasing may make sense in some cases, but is managing building maintenance cost-effective for the staff?

“When you have a lease, you might have a landlord that will build out the space and offer you incentives to rent,” says Madiah. “If you own the space, are you going to have the patient volumes to service the building? And is that really what you want to be spending your time doing?”

Improving cash flow doesn’t have to be complicated, but setting up the right system can be the difference between success and failure.

“It’s all about setting up proactive revenue cycle policies and being able to predict what your cash flow is and being proactive with the entire process,” says Zetter. “Most revenue cycle management has been and still is reactive — we chase money. And businesses that chase money don’t make money, and they don’t stay in business.”

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Navigating the gauntlet: Coding and documentation best practices

Introduction:
The difference between a financially and clinically successful practice and one that is struggling often comes down to whether they have the code right and document thoroughly. Changes in 2021 to major coding categories, such as evaluation and management (E/M) coding for office visits means major change that can hamper your operations if not done well. Denials, one of the major aggravation points for practices, are possible with any filed claim, especially since each payer has their own policies, which change constantly.

What can practices do to tighten up their coding and realize all the revenue they are owed?

Learning objectives
- Understand E/M coding changes and what it means to the bottom line.
- Learn the most common reasons for claim denials and how to prevent them.

Meet the panelist
Bill Dacey, M.H.A., MBA, CPC, CPC-I, principal of The Dacey Group, Inc., a consulting firm specializing in physician coding and compliance

Coding and documenting best practices
The E/M changes that went into effect in January were designed to simplify the process and can be a financial net win for practices. Now, physicians will select the correct level-of-care code based on total time spent on the date of the encounter or medical decision-making (MDM) —whichever is most financially advantageous.

Regarding E/M coding, Dacey recommends that practices understand the intricacies of coding by time and MDM. (For a detailed breakdown, including coding tables, check out the full video and slide deck on MedicalEconomics.com.)

Beyond coding these aspects correctly, the other issue for practices is that some of the documentation categories that are no longer relevant for payment remain relevant on a clinical basis, Dacey notes. “We know history and exam are no longer relevant for code selection, but you still have to do each for every encounter,” he says. “We’re assuming that the note is still going to have everything in it that it needs from a clinical perspective. Some doctors have just completely abandoned it and just have an assessment plan. That’s not really OK because you still need to have enough to support the clinical element of things, and it also doesn’t tell the payer the whole story of what that encounter is all about.”
Another episode of overt hepatic encephalopathy (OHE) may be right around the corner. What can you do to reduce your patient’s risk of recurrence?

Align with the guidelines for patients at risk

XIFAXAN earned AASLD/EASL’s highest possible recommendation (GRADE I,A,1) as an add-on therapy to lactulose to reduce the risk of overt HE recurrence after a patient has a recurrence while on lactulose alone.1*

*Per the GRADE System for Evidence: Grade I=randomized, controlled trials; A=evidence is “high quality,” and further research is very unlikely to change our confidence in the estimated effect; and 1=recommendation is “strong,” with factors influencing strength of recommendation including the quality of evidence, presumed patient-important outcomes, and costs.

INDICATION

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.

- Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued.

- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.

XIFAXAN is the only FDA-approved agent indicated for the reduction in risk of OHE recurrence in adults.1

In a clinical trial of adults, XIFAXAN cut the risk of OHE recurrence and HE-related hospitalizations in half2

91% of patients in the placebo and XIFAXAN groups were on lactulose2

Study design1,2
- In a randomized, placebo-controlled, double-blind, multicenter, multinational, 6-month study, the efficacy of XIFAXAN 550 mg (taken orally twice a day) was evaluated in 299 adult subjects
- Inclusion criteria: Currently in remission (Conn score of 0 or 1) from HE and ≥2 episodes of HE associated with chronic liver disease in the previous 6 months
- Primary endpoint: Time to first breakthrough overt HE episode, defined as a marked deterioration in neurological function (an increase in Conn score to grade ≥2 or an increase in Conn score and asterixis grade of 1 each if subject entered study at grade 0)
- Key secondary endpoint: HE-related hospitalization

IMPORTANT SAFETY INFORMATION (continued)
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In a clinical study, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see brief summary of full Prescribing Information on the following pages.

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**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

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

XIFAXAN® (rifaximin) tablets, for oral use

**Indications and Usage**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XIFAXAN, XIFAXAN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

1 **INDICATIONS AND USAGE**

1.2 Hepatic Encephalopathy

XIFAXAN is indicated for reduction in risk of overt hepatic encephalopathy in adults.

2 **CONTRAINDICATIONS**

XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycins, antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioedema, anaphylaxis. [see Adverse Reactions (6.2)].

3 **WARNINGS AND PRECAUTIONS**

5.2 Clostridium difficile-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN. CDAD manifestations range from moderate illnesses like mild diffuse colitis to severe colitis with life-threatening large intestine complications. Treatment with antibacterial agents alters the normal flora of the colon which may lead to overgrowth of C. difficile. C. difficile colonization of the gut may cause line colonization with A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur as long as several months or more following the administration of antibacterials. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, and antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

5.4 Severe (Child-Pugh Class C) Hepatic Impairment

There is limited experience in patients with severe hepatic impairment. The clinical trials were limited to patients with moderate (Child-Pugh Class B) and severe (Child-Pugh Class C) hepatic impairment, respectively, compared to that in healthy volunteers. No dosage adjustment is recommended because rifaximin is presumably acting locally. Nonetheless, caution should be exercised when rifaximin is administered to patients with severe hepatic impairment. [see Use in Specific Populations (8.7), Clinical Studies (14.2)].

5.5 Concomitant Use with P-glycoprotein Inhibitors

Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs significantly increases the exposure of rifaximin in patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin. Should be exercised when concomitant use of XIFAXAN and a P-gp inhibitor such as cyclosporine is needed. [see Warnings and Precautions (5.5), Clinical Pharmacology (12.3)].

7.2 Warfarin

Changes in INR have been reported postmarketing in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be needed to maintain target INR range. See prescribing information for warfarin.

7.3 CYP3A4 Substrates

An in vitro study has suggested that rifaximin induces CYP3A4. [see Clinical Pharmacology (12.3)]. However, in patients with normal liver function, rifaximin's recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates with reduced liver function who have elevated rifaximin concentrations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data available on XIFAXAN use in pregnant women to inform drug-associated risks. Teratogenic effects were observed in animal reproduction studies following administration of rifaximin to pregnant rats and rabbits during organogenesis at doses approximately 0.9 to 1.3 times the human daily doses (33% to 51% of the human daily dose) adjusted for body surface area. Rifaximin was teratogenic in rabbits at doses of 62.5 to 1000 mg/kg (approximately 2 to 33 times the recommended daily human dose). Rifaximin was teratogenic in rats at doses of 150 to 300 mg/kg (approximately 2.6 times the recommended dose for HE [1,100 mg per day], and approximately 0.9 to 1.8 times the recommended daily human dose) adjusted for body surface area. Rifaximin was teratogenic in rabbits at doses of 62.5 to 1000 mg/kg (approximately 2 to 33 times the recommended daily human dose) and 2.6 times the recommended dose for HE [1,100 mg per day], and approximately 0.9 to 1.8 times the recommended daily human dose for BD (850-1,650 mg/day) adjusted for body surface area. These effects include cleft palate, agnathia, jaw shortening, hemorrhage, eye partially open, small eyes, brachynathia, incomplete ossification, and increased thoracolumbar vertebras.

8.2 Lactation

Increased blood creatine phosphokinase and increased thoracolumbar vertebrae.

9 NONCLINICAL TOXICOLOGY

9.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Mice dosed orally with rifaximin for 26 weeks at 150 to 250 mg/kg per day (doses equivalent to 0.7 to 1.5 times the recommended daily dose for HE, based on relative body surface area comparisons) showed no increase in tumors in Tg(aHR2) mice dosed orally with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to 1.3 to 2.2 times the recommended dose of 550 mg twice daily for HE, based on relative body surface area comparisons). There was no increase in tumors in Tg(aHR2) mice dosed orally with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to the recommended daily dose for HE, based on relative body surface area comparisons).

10 OVERDOSAGE

10.1 General Information

No specific information is available on the treatment of overdose with XIFAXAN. In clinical studies at doses higher than the recommended dose (greater than 1,100 mg per day for HE), adverse reactions were similar in subjects who received doses higher than the recommended dose and placebo. In the case of overdose, discontinue XIFAXAN, treat symptomatically, and institute supportive measures as required.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Mice dosed orally with rifaximin for 26 weeks at 150 to 250 mg/kg per day (doses equivalent to 0.7 to 1.5 times the recommended daily dose for HE, based on relative body surface area comparisons). There was no increase in tumors in Tg(aHR2) mice dosed orally with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to 1.3 to 2.2 times the recommended dose of 550 mg twice daily for HE, based on relative body surface area comparisons). There was no increase in tumors in Tg(aHR2) mice dosed orally with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to the recommended daily dose for HE, based on relative body surface area comparisons).

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The good news for physicians is that Medicare payments for almost every E/M level increased. For example, Dacey says reimbursement rates went up 19% for code 99213, 21% for code 99214 and 23% for code 99215, which are level-of-care codes for established patients.

The key to successfully coding under the new E/M changes is that documenting medical decision-making is key, says Dacey, noting that payers look in the assessment and plan (A/P) to see if you provided enough medical necessity to back up your claim. So be sure to do the following:

- Document any specific differential diagnosis and any suspected problems or concerns that need to be considered, ruled out, etc.
- Identify the diagnosis, status, prescriptions and treatments to manage each problem.
- Characterize the problem — don’t just name it.
- Introduce the scope in the history of present illness, and then showcase it in the A/P.

Regarding how to avoid claim denials, Dacey says that most denials are the result of basic mistakes such as filing duplicate claims, not verifying eligibility, failing to review prior authorization or missing the timing deadline.

“There (are) a lot of ways to go wrong here,” Dacey says. “There (are) a lot of ways to very easily get denials.”

The best thing practices can do to avoid denials is to analyze common denials and use that knowledge to build better processes. “The number and types of denials actually tell you where the weak parts are in your machine, what part of your operation needs to get sharper,” he says.

Dacey also points out that while some denials are simple, others are incredibly complex and can affect downstream care, i.e., hepatic encephalopathy (HE). Because of diagnostic coding changes on the transition to ICD-10 some years ago, there is no longer a “pure” HE code; thus, incorrect coding for this condition is leading to prior authorizations, which is leading to patients not receiving the treatment they need and ending up in the hospital. Using the recommended ICD-10 codes for HE patients who are in a coma (K72.91) or not (K72.90) is crucial.

“The number and types of denials actually tell you where the weak parts are in your machine, what part of your operation needs to get sharper.”

Dacey emphasizes that the key to a coding and documentation program that captures all revenue is not looking for ways to cut corners or for little missed opportunities but, rather, getting it right on the most common patient visits you have.

“Everybody is always looking for ways to cut corners and those little extra things you can do,” he says. “And I keep telling people, ‘Stop looking over there, and look right back at what you do all day long — and make sure you have the big ones right.’”

**Solutions and takeaways:**

- Changes in 2021 to E/M office visit coding mean that medical decision-making and time are key to getting paid, but other aspects such as history of present illness, assessment and plan are still necessary for appropriate clinical care.
- Most denials are caused by common mistakes, and the best way to avoid them are to put processes in place to flag the most common reasons for denials in your practice and address them.
Revenue cycle management: How to collect more from patients and payers

Introduction
Collecting what is owed from patients and payers has long been a headache for medical practices. But in recent years, it has become even more difficult due to two overlapping trends. The first is that patients are having to shoulder ever-larger shares of their health costs. According to a Kaiser Health Tracker survey, health costs incurred by families with insurance coverage from large employers — including premium contributions and out-of-pocket spending on health services — increased by 67% from 2008 to 2018.

At the same time, payers have been requiring more and more time-consuming prior authorizations before they will pay for a service, procedure or prescription medication. This is evidenced by a 2019 American Medical Association survey in which 86% of responding doctors said their prior authorization burden had increased over the past five years.

Considering these developments, it’s more important than ever for practices to ensure that their collection technology and processes are streamlined, user-friendly and up-to-date. This strategy can go a long way toward ensuring a practice’s long-term financial viability.

Learning objectives:
- Revenue cycle management (RCM) explained.
- Practical tips to financially assess your practice.
- How to select the best RCM partner for you.

Meet the panelist: Andrew Harding, vice president of customer success, Rivet Health

How practices can plug the sources of ‘revenue leakage’
When Benjamin Franklin coined the phrase, “An ounce of prevention is worth a pound of cure” he was referring to fire prevention. But that same logic applies to medical practices when it comes to maximizing collections: Investing a little effort at the start of the process avoids having to spend much more time and energy later.

According to Andrew Harding, vice president of customer success for Rivet Health, “revenue leakage” for medical practices has two primary sources — difficulty collecting directly from patients and payers’ claims denials. Collecting from patients has gotten harder in recent years, Harding says, due in part to the growth of high-deductible health plans (HDHPs), which make patients responsible for large portions of their bills. He cites a 2017 Black Book survey in which 83% of practices with fewer than five practitioners said that slow payments from patients with HDHPs are their top collection challenge.

Moreover, he notes, collection rates decline dramatically the further out you get from when a patient was billed. That makes it important for practices to collect as much as possible from patients early in the process and to prepare patients for what they will owe by providing upfront cost estimates. Harding explains that providers can calculate these by pairing the patient’s benefit eligibility with the provider’s adjusted contractual allowable.
Rivet is a modern revenue cycle product suite that gives you payer superpowers to unlock more revenue from patients and payers.

“Rivet has driven up revenue massively. It paid for itself in less than a month.

The biggest thing is that we're getting paid what we're supposed to and Rivet helps with that.”

— Jennifer Davison, CEO of VERO Orthopaedics

Find out more at rivethealth.com.
Practices can also up their collection rates by giving patients multiple payment avenues, including phone, portals or point of service, and by helping patients understand both their benefits and payment responsibilities. “It’s surprising the number of patients who don’t understand the connections between deduction, coinsurance and out-of-pocket maximum,” he says.

“Revenue leakage for medical practices has two primary sources — difficulty collecting directly from patients and payers’ claims denials.”

Harding says the other source of revenue leakage, claims denials, has been on the rise, citing a Change Healthcare study that found the average national rate increased from 9% in 2016 to 10.8% in the second quarter of 2020. Close to half of all denials, he adds, are the result of front-end revenue cycle issues, such as registration errors, incorrect demographics information and missing referrals. “That means right out of the gate at least half of your denials are preventable because they stem from missed or incorrect or unverified data,” he notes.

Harding recommends following these steps to reduce claims denials:
- Identify the top causes of denials.
- Implement measures for addressing those causes, such as improving registration and financial clearance processes and pre-bill edits.
- Ask members of the practice’s claims denials team how they would work various types of denials and to document and share the responses. “It’s astounding the number of times we’ve seen different people have different appeals processes for the exact same payer and denial,” Harding says.
- Identify the processes that have the best appeal or recovery rate, and implement those across the denials team.
- Make information pertaining to every denial — such as the claim, provider, diagnosis and payer, and the steps taken to resolve the denial — available on one computer screen to easily accessed by every member of the denial team.
- Evaluate the electronic health record’s work queue to ensure that deadlines for appealing claims denials are met. “No claim should miss the timely appeal window because you should have a work queue in place that identifies when an appeal is starting to age out,” Harding says.

**Solutions and takeaways:**
- Communicate with patients prior to service, including your best estimate of costs and information about your practice’s payment policies.
- Make it easy for patients to pay by providing multiple payment platforms and technologies.
- Review claims denials and identify the top reason(s) for them.
- Query staffers who handle claim denials to find the best recovery strategies for each payer and share that information with other members of the team.
- Organize the claims denials workflow so that all necessary information is easily available to the person addressing the denial.

**MORE ONLINE:**
Check out the full video and materials of this session and eight other Bootcamp sessions.
Remote patient monitoring fitness test

Introduction:
Interest in remote patient monitoring (RPM) — using digital technologies to track and capture patients’ medical/health data and electronically transmitting it to their health care providers — has been growing for years. But it accelerated in 2020 with the steep decline in in-person patient visits brought on by COVID-19, which forced health care providers to find alternative ways of monitoring patients’ health.

The growth is reflected in a July forecast from ResearchAndMarkets.com that predicted the market for RPM devices will reach $85 billion by the end of 2026, up from just over $20 billion in 2019, or an annual compound rate of nearly 23%.

Similarly, a March VivaLNK survey of hospitals and clinics found that 43% believe RPM adoption will be on par with in-patient monitoring in five years, and 35% believe it will surpass in-patient monitoring.

Along with its benefits for patients’ health, RPM offers the opportunity to become a significant revenue stream for practices. But turning that possibility into reality requires careful organizational planning, gaining acceptance from providers and staff and educating patients on what RPM requires of them and how they will benefit from it.

Learning objectives
- RPM explained: the benefits and the challenges.
- How to reach patients and achieve buy-in and participation.
- Revenue implications and strategies to create a sustainable program.

Meet the panelists
Todd Haedrich, CEO, Optimize Health
Neha Ajmera, MBA, senior vice president of operations, Optimize Health
Ryan Clark, vice president of customer success, Optimize Health
Kaitlyn O’Connor, J.D., senior counsel, Nixon Gwilt Law

Get buy-in from staff and patients
RPM can be an effective tool for improving patient outcomes and driving practice revenue. But implementing a successful RPM program requires careful internal preparation and taking the time to instruct patients on how to use monitoring devices and report their data.

“If you think RPM is right for you, you need to make certain that your providers and staff are educated on what it is (and) how to identify patients that will benefit clinically from an RPM program and that they can educate patients and incorporate RPM into the patients’ care programs,” says Ryan Clark, vice president of customer success at Optimize Health.

Building an effective RPM program starts with getting organizational buy-in, says Clark. “Talk about it with all the impacted areas in your practice. Make sure you have the bandwidth and your clinical staff are all bought in. Start that conversation broadly and early.”

Clark advises identifying clinical and operational “champions,” with the latter being the main point of contact for anyone involved in the program either internally or externally.

At the same time, Clark says, patients need to become partners in managing their health and be educated on how RPM can help them and what’s expected of them. “Is it taking daily readings if they’re trying to manage blood sugar? Do they take them before or after meals? There’s all kinds of patient education that goes into this, and you need to empower your team to speak to that and make patients feel like they have ownership in getting their condition under control,” he says.

Once an RPM program is up and running, it’s important to invest in its maintenance and monitor its results. “You obviously want to track the patient outcomes from the program,”
Clark says. In addition, “as more patients come on to the program and you identify additional clinical needs, (you want to ensure) you have the right devices to meet those needs and to measure your reimbursement success and the success of the patient care plans.”

Neha Ajmera, MBA, senior vice president of operations for Optimize Health, says practices most commonly use RPM to manage patients with chronic diseases and/or acute conditions and following discharge from a hospital or nursing facility. Since the start of the COVID-19 pandemic, RPM has also been used to monitor patients with COVID-19 or its symptoms or who have been exposed to the virus.

From the patient perspective, Ajmera says, RPM works best for those who:
- Have an acute condition that can improve with frequent measurements and clinical interventions as needed.
- Have a chronic condition that can be improved with additional data and coaching.
- Are motivated to take responsibility for their health and understand the benefits and expectations of an RPM program

“Ultimately RPM is a partnership between the patient and provider that’s made deeper because of real-time data,” she says.

Kaitlyn O’Connor, J.D., a health care attorney with the Nixon Gwilt Law, says that RPM-related services are covered by five current procedural terminology, or CPT, codes with varying levels of reimbursement. These range from $19 for “initial setup and patient education on use of equipment” (code 99453) to $63 for “device(s) supply with daily recording(s) or programmed alert transmission, each 30 days” (99454).

She adds that Medicare and commercial payers recognize RPM’s value in maintaining patients’ health and improving outcomes and are willing to reimburse for it at relatively high levels. Moreover, by providing physicians with regular data about patients’ health, RPM can reduce costly hospitalizations and emergency department visits.

“Ultimately RPM is a partnership between the patient and provider that’s made deeper because of real-time data.”

She cites studies showing that hospital readmission rates for patients with heart failure using RPM were less than a third of those without RPM. Among patients with chronic obstructive pulmonary disease, the rates were less than half. Consequently, O’Connor says, the Centers for Medicare & Medicaid Services has made RPM a “strategic priority” in its effort to reduce Medicare costs, which are on course to double over the next decade.

### Hospital readmission rates

<table>
<thead>
<tr>
<th>Condition</th>
<th>For COPD patients with RPM</th>
<th>Without RPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD</td>
<td>6.7%</td>
<td>14.1%</td>
</tr>
<tr>
<td>Heart failure</td>
<td>4.2%</td>
<td>13.8%</td>
</tr>
</tbody>
</table>

COPD, chronic obstructive pulmonary disease; RPM, remote patient monitoring.

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**Solutions and takeaways**

- Get buy-in for an RPM program from every part of your organization.
- Identify an RPM program champion and build a team around that individual.
- Educate patients on what RPM requires of them and how they can benefit from it.
- Dedicate a team member or members time to RPM monitoring and patient engagement.
- Invest in the program’s management and growth.
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Earning your stripes: Wealth building and retirement planning

Introduction:
Physicians are often at a disadvantage when it comes to retirement planning compared to other professionals because they enter the workforce later in life and typically carry a lot of debt. In fact, the average medical student graduates with more than $200,000 in debt.

Regardless of where physicians are in their career, it’s never too late to start planning for the day when they hang up their stethoscope and retire. In addition to retirement, physicians also need to protect their family’s financial future with a solid estate plan that retains the wealth they have worked so hard to accumulate.

With a strong investment plan and a financial strategy that minimizes taxes, it’s possible for physicians to achieve all their financial dreams.

Learning objectives
- How to prepare for retirement at any stage of your career
- Estate planning 101: Protecting your family’s financial future
- Investment and tax minimization tips

Meet the panelist
Joel Greenwald, M.D., CFP
Greenwald Wealth Management

Take these key steps to ensure a financially secure retirement
The No. 1 question physicians ask about retirement is, “How much money will I need to retire?”

The answer can widely vary depending on a host of factors, including age and spending levels. Creating long-term projections can be complicated, so physicians might rely on a simple rule of thumb, such as the 4% rule — essentially taking out 4% of your retirement savings each year — to simplify things.

Joel Greenwald, M.D., CFP, says that kind of oversimplification can lead to running out of money in retirement. “Unfortunately, as with any rule of thumb, particularly ones that are simple, they’re not entirely reliable,” says Greenwald.

For example, the 4% rule only covers a maximum of 30 years of retirement. “People seem to extend that to 35 or 40 years of retirement, which certainly can happen now with people retiring earlier and particularly with longevity,” he says. That, however, means they will most likely run out of money.

In addition, the type of account holding the money can affect the calculations because taxes may take a larger share of the money than anticipated. On the flip side, physicians may die with too much money, meaning they may have missed out on a lot of experiences for fear of running out of funds in retirement.

One of the best strategies to make sure you have the right amount of money is to ask a slightly different question. “It isn’t, ‘How much can (I) safely withdraw from a nest egg at retirement?’ ” says Greenwald. “It’s, ‘How much do I need to be saving every year during my working years, during my accumulation years, so that I make sure I have enough money?’”
In most cases, saving 20% of your gross income allows you to retire in your 60s. And the quickest way to get to that 20% is to automatically invest into a growth-oriented brokerage account each month.

“The reason it needs to be automatic is because a lot of people say, ‘OK, I’m going to get through the year, and at the end of the year, any extra money I have, I (will) put in my investment account,’” says Greenwald. “Lo and behold, come the end of the year, there is no money for the investment account.” The automatic investment ensures the money is not spent and, instead, compounds over time to grow retirement savings.

“It isn’t, ‘How much can (I) safely withdraw from a nest egg at retirement? It’s, ‘How much do I need to be saving every year during my working years ... so that I have enough money?’”

Joel Greenwald, M.D., CFP

Another good strategy is to plan for market downturns so that you don’t have to withdraw money from your investment accounts. “What some folks advocate is having a year or two at least of spending in cash or in short-term bonds, so that when you retire or soon after you retire, (if) the market goes down, you’re not having to sell stocks to pay the bills. You’ve got money on the side,” says Greenwald.

Physicians also need a long-term tax strategy to minimize impact and should consult with an accountant who has experience working with doctors on this. “Rather than looking simply at, ‘How do I save on this tax?’ people need to look bigger picture,” says Greenwald. “What things can you be doing over a lifetime to save on taxes?”

The other financial piece that physicians often overlook is creating a solid estate plan. For younger, married physicians with no children, having a financial power of attorney and a health care directive in place is probably good enough. But for older, wealthier physicians, they will need a much more detailed plan that may include a revocable trust to hold their assets. Without a proper estate plan, a lifetime of earnings may be siphoned off to taxes or held up in court. A good plan makes sure your money is protected and goes to the people you want it to go to.

**Solutions and takeaways:**
- Don’t rely on oversimplified investment guidelines to fund your retirement.
- Create a long-term investment plan that includes money for contingencies and market swings.
- Analyze your spending patterns now to better understand your retirement needs.
- Approach tax-planning with a long-term view.
- Form a rock-solid estate plan to protect your wealth.

**More Online:**
Check out the full video and materials of this session and eight other Bootcamp sessions.
Biologics for the treatment of inflammatory bowel disease

by Grace Halsey Senior Editor

Welcome to “Around the Practice,” an interactive video program that features trends in the field, debates on chronic condition management, and more.

The following transcript features three physicians discussing the clinical features of inflammatory bowel disease, differential diagnosis of ulcerative colitis and Crohn’s disease, challenges in disease management and appropriate strategies for optimizing treatment. They also explain their approach to a hypothetical patient case. The transcript of the video recording was edited for length and clarity.

The moderator is Joseph Feuerstein, M.D., associate professor of medicine at Harvard Medical School in Boston.

Our panelists are as follows:

Stephen B. Hanauer, M.D., medical director of the Digestive Health Center at Northwestern Memorial Hospital in Chicago

Ryan Ungaro, M.D., assistant professor of medicine in the division of gastroenterology at Icahn School of Medicine at Mount Sinai in New York

Bruce Sands, M.D., professor of medicine and chief of Dr Henry D. Janowitz Division of Gastroenterology at Icahn School of Medicine at Mount Sinai in New York.

Feuerstein: I’d like to begin our discussion with a brief review of the pathophysiology of inflammatory bowel disease and of risk factors and characteristics associated with development of the disease.

Hanauer: Let’s begin with the concept that inflammatory bowel disease encompasses both ulcerative colitis and Crohn’s disease, which are two distinct but often overlapping conditions. Ulcerative colitis is a diffuse, continuous, superficial inflammation involving the colon that always begins in the rectum and may include a more proximal amount of the colon that varies among individuals. Crohn’s disease is a transmural disease, meaning it includes both superficial inflammation and inflammation through the bowel wall that lead to complications that can include both strictures and fistula. Crohn’s disease can affect any portion of the GI (gastrointestinal) tract.

Both have a genetic component, probably more so in Crohn’s disease. The gene mutations account for only about 15% of patients who have inflammatory bowel disease.

Additional factors are quite varied. We don’t know of any specific diet factors associated with these diseases. However, we know that nonsteroidal anti-inflammatory drugs can make the conditions worse or even resemble inflammatory bowel disease.
Feuerstein: What role do genetics and the environment play in the development of inflammatory bowel disease?

Sands: We’ve long known that inflammatory bowel (IBD) disease tends to run in families. In fact, about 1 of 5 patients may tell you that they have a family member, whether first degree or more distant, who may be affected. The risk of familial occurrence is a little higher in Crohn’s disease than in ulcerative colitis.

But sometimes you’ll find families where some individuals have Crohn’s disease and others have ulcerative colitis. This suggests a commonality of the genetics from the beginning, and if you look at the genetic architecture elucidated over the last 15 years, you’ll find that most of the genes that incrementally increase risk for IBD are common between ulcerative colitis and Crohn’s disease.

There are some genetic risk loci unique to Crohn’s and a handful unique to ulcerative colitis. But genetic testing generally isn’t very helpful in making a diagnosis. I wouldn’t consider that to be routine in clinical care.

Genetics also suggest that a host response to the bacterial flora in the gut is aberrant. We know this from the first gene discovered and described as a risk factor for Crohn’s disease, the NOD2 gene, which is an intracellular bacterial sensor. We don’t know what it is about the bacterial flora that may be wrong, but most patients have a dysbiosis.

Differential diagnosis of IBD and referral

Feuerstein: How is the diagnosis made for ulcerative colitis and Crohn’s disease? What are red-flag symptoms that should prompt a primary care clinician to refer a patient to a gastroenterologist for potential IBD?

Ungaro: There is a broad differential diagnosis with both diseases. Primary symptoms like diarrhea, bloody stool and abdominal pain can be symptoms for multiple diseases. The first thing to consider in a patient with this presentation is infection. And to rule out infection, standard stool tests are something to consider.

In the noninfectious realm, conditions that could present with similar symptoms to IBD are more systemic — vasculitides or other immune-mediated diseases like sarcoidosis. You could also have common conditions like irritable bowel syndrome presenting similarly to IBD. Other things can lead to colonic inflammation, like NSAID (nonsteroidal anti-inflammatory drug)-induced enteritis or colitis, ischemic colitis and other localized inflammatory conditions of the colon like microscopic colitis.

The gold standard to differentiate among these is endoscopy or colonoscopy, which allows direct visualization of the ileal mucosa and colon (and) of the appearance of the lesions and also allows tissue biopsies. For both ulcerative colitis and Crohn’s disease, you’re looking for chronicity of inflammation. The pathology report will indicate things such as distortion of the crypt architecture of the lining of the intestine and the presence of chronic inflammatory cells like lymphocytes, as opposed to more acute infiltrates.

Hanauer: When a primary care clinician is seeing a patient with diarrhea and abdominal pain, the most common diagnosis is going to be something like irritable bowel syndrome. As gastroenterologists, we look for red-flag conditions associated with inflammation such as bleeding, nocturnal bowel movements, weight loss or extraintestinal manifestations such as arthritis or skin conditions. Those would be reasons to refer to a gastroenterologist directly to try to make a diagnosis of an inflammatory condition.

Ungaro: One last thing, which can be done very easily in the primary care setting, is a test that is underutilized — a stool calprotectin. Fecal calprotectin, if that’s elevated, is telling you that there’s an inflammatory condition somewhere in the intestine most likely going on. That would be someone to refer to a GI doctor sooner rather than later.

Feuerstein: Are there other biomarkers or non-invasive tests that can assist in the diagnosis of ulcerative colitis or Crohn’s disease?

Sands: We talked about fecal calprotectin, which is a marker of neutrophils. Neutrophilic infiltration is part of the inflammation, especially in colonic disease, but also to some degree in small-bowel Crohn’s disease. If there’s an elevation above 55 μg/mg, that would lead you to evaluate very closely whether the patient has IBD.

You can use CRP (C-reactive protein) level and ESR (erythrocyte sedimentation rate). But not everyone will manifest these. About 30% of the population doesn’t even generate CRP genetically, even if they have inflammation. It’s not a very sensitive marker, and neither is sed rate. These blood tests are a little better for Crohn’s disease as a biomarker than they are for ulcerative colitis.
Clinical Response† at Week 8 in UC (Major Secondary Endpoint):
• STELARA®: 58% (n=186/322); Placebo: 31% (n=99/319); P<0.001

Clinical Remission‡ at Week 8 in UC (Primary Endpoint):
• STELARA®: 19% (n=62/322); Placebo: 7% (n=22/319); P<0.001

Clinical Remission‡ at 1 Year in UC (Primary Endpoint):
• STELARA®: 45% (n=79/176); Placebo: 26% (n=46/175); P<0.001

HEMI§ at Week 8 (Overall Population) in UC (Other Secondary Endpoint):
• STELARA®: 17% (n=54/322); Placebo: 8% (n=26/319); P<0.001

The relationship of HEMI to long-term outcomes was not studied in the clinical trials.

UC Study Designs:
In UC-1 (Induction Study, 8 Weeks), 961 patients were randomized to either a single placebo IV (n=319) or STELARA® IV dose (based on the body weight of the patient at the time of dosing) of approximately 6 mg/kg administered over at least 1 hour at Week 0 (n=322). Eligible patients (≥18 years of age) had moderately to severely active UC (ie, Mayo score of 6 to 12, including a Mayo endoscopy subscore ≥2) and had experienced an inadequate response to or failed to tolerate previous biologics (ie, TNF blocker and/or vedolizumab), corticosteroids, and/or 6-mercaptopurine or azathioprine therapy. In UC-2 (Maintenance Study, 44 Weeks), 523 patients who achieved clinical response 8 weeks following the IV administration of the induction dose of STELARA® in UC-1 were randomized to receive STELARA® 90 mg q8w (n=176) or placebo (n=175) for 44 weeks. After completing the Maintenance Study at Week 44, patients were eligible to enter the open-label LTE study.

Clinical Response† at Week 6 (Predominantly TNF Blocker Naïve) in CD (Primary Endpoint):
• STELARA®: 56% (n=116/209); Placebo: 29% (n=60/209); P<0.001

Clinical Response† at Week 6 (TNF Blocker Failure) in CD (Primary Endpoint):
• STELARA®: 34% (n=84/249); Placebo: 21% (n=53/247); P<0.01

Clinical Remission‡ at 1 Year (Overall Population) in CD (Primary Endpoint):
• STELARA®: 53% (n=68/128); Placebo: 36% (n=47/131); P<0.01

CD Study Designs: In CD-1 and CD-2 (Induction Studies, 8 Weeks), 741 and 627 patients, respectively, were randomized to either a single placebo IV (n=247, n=209) or STELARA® IV dose (based on the body weight of the patient at the time of dosing) of approximately 6 mg/kg administered over at least 1 hour at Week 0 (n=249, n=209). Eligible patients (≥18 years of age) had moderately to severely active CD (CDAI score of 220 to 250) and had failed or were intolerant to treatment with one or more TNF blockers (CD-1) or had failed or were intolerant to treatment with immunomodulators and/or corticosteroids, but never failed treatment with a TNF blocker (CD-2). In CD-3 (Maintenance Study, 44 Weeks), 388 patients who had achieved clinical response (≥100 point reduction in CDAI score) at Week 8 with the induction dose of STELARA® in CD-1 or CD-2 were randomized to receive a subQ maintenance regimen of either 90 mg of STELARA® q8w (n=128) or placebo (n=131) for 44 weeks. After completing the Maintenance Study at Week 44, patients were eligible to enter the open-label LTE study.

Clinical Response† at Week 8 in UC (Major Secondary Endpoint):
• STELARA®: 58% (n=186/322); Placebo: 31% (n=99/319); P<0.001

Clinical Remission‡ at Week 8 in UC (Primary Endpoint):
• STELARA®: 19% (n=62/322); Placebo: 7% (n=22/319); P<0.001

Clinical Remission‡ at 1 Year in UC (Primary Endpoint):
• STELARA®: 45% (n=79/176); Placebo: 26% (n=46/175); P<0.001

HEMI§ at Week 8 (Overall Population) in UC (Other Secondary Endpoint):
• STELARA®: 17% (n=54/322); Placebo: 8% (n=26/319); P<0.001

HEMI§ at 1 Year (Overall Population) in UC (Prespecified Other Endpoint; not adjusted for multiplicity):
• STELARA®: 44% (n=75/172); Placebo: 23% (n=40/172)

The relationship of HEMI to long-term outcomes was not studied in the clinical trials.

CD Study Designs: In UC-1 (Induction Study, 8 Weeks), 961 patients were randomized to either a single placebo IV (n=247, n=209) or STELARA® IV dose (based on the body weight of the patient at the time of dosing) of approximately 6 mg/kg administered over at least 1 hour at Week 0 (n=249, n=209). Eligible patients (≥18 years of age) had moderately to severely active UC (ie, Mayo score of 6 to 12, including a Mayo endoscopy subscore ≥2) and had experienced an inadequate response to or failed to tolerate previous biologics (ie, TNF blocker and/or vedolizumab), corticosteroids, and/or 6-mercaptopurine or azathioprine therapy. In UC-2 (Maintenance Study, 44 Weeks), 523 patients who achieved clinical response 8 weeks following the IV administration of the induction dose of STELARA® in UC-1 were randomized to receive STELARA® 90 mg q8w (n=176) or placebo (n=175) for 44 weeks. After completing the Maintenance Study at Week 44, patients were eligible to enter the open-label LTE study.
HISTO-ENDOSCOPIC MUCOSAL IMPROVEMENT (HEMI) IN UC

The first and only FDA-approved UC treatment to achieve HEMI. Some patients with UC achieved HEMI with STELARA® at the designated time points (Week 8 and 1 year) in clinical trials. The relationship of HEMI to long-term outcomes was not studied in the clinical trials.

SAFETY PROFILE

The overall safety profile in CD and UC studies through 1 year was consistent with that seen in other approved indications.

INDICATIONS

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease. STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

SELECTED IMPORTANT SAFETY INFORMATION

STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Serious adverse reactions have been reported in STELARA®-treated patients, including bacterial, mycobacterial, fungal, and viral infections, malignancies, hypersensitivity reactions, Posterior Reversible Encephalopathy Syndrome (PRES), and noninfectious pneumonia. STELARA® should not be given to patients with any clinically important active infection. Patients should be evaluated for tuberculosis prior to initiating treatment with STELARA®. Live vaccines should not be given to patients receiving STELARA®. If PRES is suspected or if noninfectious pneumonia is confirmed, discontinue STELARA®.

Please see related and other Important Safety Information on next page.


CD=Crohn’s disease; CDAI=Crohn’s Disease Activity Index; HEMI=histo-endoscopic mucosal improvement; IV=intravenous; LTE=long-term extension; q8w=every 8 weeks; subQ=subcutaneous; TNF=tumor necrosis factor; UC=ulcerative colitis.
**IMPORTANT SAFETY INFORMATION**

**STELARA® (ustekinumab)** is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or any of the excipients.

**Infections**

STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn’s disease, these included anal abscess, gastroenteritis, ophtalmic herpes zoster, pneumonia, and *Listeria* meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophtalmic herpes zoster, pneumonia, and listeriosis.

Treatment with STELARA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of STELARA® in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with STELARA® and consider discontinuing STELARA® for serious or clinically significant infections until the infection resolves or is adequately treated.

**Theoretical Risk for Vulnerability to Particular Infections**

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, *Salmonella*, and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered (eg, tissue culture, stool culture) as dictated by clinical circumstances.

**Pre-Treatment Evaluation of Tuberculosis (TB)**

Evaluate patients for TB prior to initiating treatment with STELARA®. Do not administer STELARA® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STELARA®. Closely monitor patients receiving STELARA® for signs and symptoms of active TB during and after treatment.

**Malignancies**

STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STELARA® in clinical studies. The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STELARA®, especially those >60 years or those with a history of PUVA or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

**Hypersensitivity Reactions**

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with STELARA®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA®.

**Posterior Reversible Encephalopathy Syndrome (PRES)**

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis and Crohn’s disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with STELARA® for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STELARA®.

**Immunizations**

Prior to initiating therapy with STELARA®, patients should receive all age-appropriate immunizations recommended by current guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment or within one year of initiating or discontinuing STELARA®. Exercise caution when administering live vaccines to household contacts of STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease.

**Concomitant Therapies**

The safety of STELARA® in combination with other biologic immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant methotrexate use did not appear to influence the safety or efficacy of STELARA®. In Crohn’s disease and ulcerative colitis induction studies, concomitant use of 6-mercaptopurine, azathioprine, methotrexate, and corticosteroids did not appear to influence the overall safety or efficacy of STELARA®.

**Noninfectious Pneumonia**

Cases of interstitial pneumonia, eosphinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of STELARA®. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and, in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue STELARA® and institute appropriate treatment.

**Allergen Immunotherapy**

STELARA® may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

**Most Common Adverse Reactions**

The most common adverse reactions (≥3% and higher than that with placebo) in adults from psoriasis clinical studies for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. The safety profile in pediatric patients with plaque psoriasis was similar to that of adults with plaque psoriasis. In psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® when compared with placebo (3% vs 1% for both). In Crohn’s disease induction studies, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn’s disease maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 for STELARA® 90 mg subcutaneous injection or placebo were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%) and sinusitis (3% vs 2%). In the ulcerative colitis induction study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance study, common adverse reactions (3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 for STELARA® 90 mg subcutaneous injection or placebo included: nasopharyngitis (24% vs 20%), headache (10% vs 4%), abdominal pain (7% vs 3%), influenza (6% vs 5%), fever (5% vs 4%), diarrhea (4% vs 1%), sinusitis (4% vs 1%), fatigue (4% vs 2%) and nausea (3% vs 2%).

Please see full Prescribing Information and Medication Guide for STELARA® at STELARAHCP.com. Provide the Medication Guide to your patients and encourage discussion.

Stelara

(Ustekinumab)

**Please see full Prescribing Information and Medication Guide for STELARA® at STELARAHCP.com. Provide the Medication Guide to your patients and encourage discussion.**

Stelara

(Ustekinumab)

Please see full Prescribing Information and Medication Guide for STELARA® at STELARAHCP.com. Provide the Medication Guide to your patients and encourage discussion.
Brief Summary of Prescribing Information for STELARA® (ustekinumab)

STELARA® is indicated for the treatment of patients 6 years or older with moderate to severely plaque psoriasis who are candidates for phototherapy or systemic therapy. STELARA® may be used as monotherapy or in combination with other anti-TNF therapy in adult patients with active psoriatic arthritis. STELARA® can be used alone or in combination with methotrexate (MTX). Crohn's Disease (CD); STELARA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease. Ulcerative Colitis: STELARA® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

CONTRAINDICATIONS: STELARA® is contraindicated in patients with a past history of latent or active tuberculosis, or for one year prior to initiating treatment or one year following discontinuation of treatment. STELARA® is contraindicated in patients who are pregnant or breastfeeding. STELARA® is not recommended for use in patients with tuberculosis infection or active tuberculosis disease.

STELARA® is not recommended for use in patients with malignancy, with the exception of low-grade lymphoma. STELARA® is not recommended for use in patients who have a history of serious infections or infections that have been inadequately treated or have resulted in significant morbidity or mortality. STELARA® is not recommended for use in patients who have a history of serious infections or infections that have been inadequately treated or have resulted in significant morbidity or mortality. STELARA® is not recommended for use in patients who have a history of serious infections or infections that have been inadequately treated or have resulted in significant morbidity or mortality.

ADVERSE REACTIONS: The following adverse reactions have been reported with STELARA® in clinical studies:

- Gastrointestinal disorders: nausea, vomiting, diarrhea, abdominal pain, flatulence.
- Cardiovascular disorders: hypertension, hypotension.
- Respiratory disorders: upper respiratory tract infection, rhinitis, pharyngitis.
- Dermatological disorders: urticaria, dermatitis, rash.
- Eye disorders: conjunctivitis, dry eye.
- General disorders and administration site reactions: fatigue, myalgia, arthralgia.

Some of the adverse reactions reported in clinical studies were found to be dose-dependent. Some of the adverse reactions reported in clinical studies were found to be dose-dependent. Some of the adverse reactions reported in clinical studies were found to be dose-dependent. Some of the adverse reactions reported in clinical studies were found to be dose-dependent. Some of the adverse reactions reported in clinical studies were found to be dose-dependent.

Table 1: Adverse Reactions Reported by ≥1% of Subjects through Week 12 in Ps STUDY 1 and Ps STUDY 2

<table>
<thead>
<tr>
<th>Subjects treated</th>
<th>Placebo</th>
<th>45 mg</th>
<th>90 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects treated</td>
<td>665</td>
<td>664</td>
<td>666</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>51 (8%)</td>
<td>56 (8%)</td>
<td>49 (7%)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>30 (5%)</td>
<td>36 (5%)</td>
<td>28 (4%)</td>
</tr>
<tr>
<td>Headache</td>
<td>33 (5%)</td>
<td>35 (5%)</td>
<td>32 (5%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>14 (2%)</td>
<td>18 (3%)</td>
<td>17 (3%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12 (2%)</td>
<td>13 (2%)</td>
<td>13 (2%)</td>
</tr>
<tr>
<td>Back pain</td>
<td>8 (1%)</td>
<td>10 (1%)</td>
<td>12 (2%)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>9 (1%)</td>
<td>9 (1%)</td>
<td>10 (2%)</td>
</tr>
<tr>
<td>Injection site erythema</td>
<td>3 (&lt;1%)</td>
<td>3 (&lt;1%)</td>
<td>1 (&lt;1%)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>4 (1%)</td>
<td>7 (1%)</td>
<td>8 (1%)</td>
</tr>
<tr>
<td>Depression</td>
<td>3 (&lt;1%)</td>
<td>8 (1%)</td>
<td>4 (1%)</td>
</tr>
</tbody>
</table>

Adverse reactions that occurred at rates less than 1% in the controlled period of Ps STUDY 1 and 2 through week 12 included: cellulitis, herpes zoster, diverticulitis and certain injection site reactions (pain, swelling, pruritus, induration, hemorrhage, bruising, and irritation). One case of PRES occurred during adult plaque psoriasis clinical studies [see Warnings and Precautions]. Infections: In the placebo-controlled period of clinical studies of psoriasis subjects (average follow-up of 12.8 weeks for placebo-treated subjects and 13.4 weeks for STELARA®-treated subjects), 27% of STELARA®-treated subjects reported infections (1.39 per subject-year of follow-up) compared with 24% of placebo-treated subjects (1.21 per subject-year of follow-up). Serious infections occurred in 0.3% of STELARA®-treated subjects (0.01 per subject-year of follow-up) and in 0.4% of placebo-treated subjects (0.02 per subject-year of follow-up) [see Warnings and Precautions].
**STELARA®** (ustekinumab)

(0.01 per subject-years of follow-up). Malignancies: In the controlled and non-controlled portions of psoriasis clinical studies (median follow-up of 3.2 years, representing 8,998 subject-years of exposure), 1.7% of STELARA®-treated subjects reported malignancies excluding non-melanoma skin cancers (0.60 per hundred subject-years of follow-up). Non-melanoma skin cancer was reported in 1.5% of STELARA®-treated subjects (0.52 per hundred subject-years of follow-up) [see Warnings and Precautions].

The most frequently observed malignancies other than non-melanoma skin cancer during the clinical studies were: prostate, melanoma, colorectal and breast. Malignancies other than non-melanoma skin cancer in STELARA®-treated patients during the controlled and uncontrolled portions of studies were similar in type and number to what would be expected in the general U.S. population according to the SEER database (adjusted for age, gender, and race). 2 Pediatric Subjects with Psoriasis: The safety of STELARA® was assessed in two studies of pediatric subjects with moderate to severe plaque psoriasis. In a study in children aged 2 to 11 years old, 157 children received STELARA® 90 mg/kg as a weight-based single maintenance dose every 8 weeks, 81 children received placebo. 3.2 years, representing 8,998 subject-years of exposure), 1.7% of STELARA®-treated subjects (0.64 events per hundred patient-years) and in 0.2% of placebo-treated subjects (0.40 events per hundred patient-years).

**DRUG INTERACTIONS:** 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 ustekinumab in the studies reported below with the incidence of antibodies reported in other studies may be misleading. Approximately 6 to 12.4% of subjects treated with STELARA® in psoriasis and psoriatic arthritis clinical studies developed antibodies to ustekinumab, which were generally low-titer. In psoriasis clinical studies, antibodies to ustekinumab were associated with reduced or undetectable serum ustekinumab concentrations and reduced efficacy. In psoriasis studies, the majority of subjects who were positive for antibodies to ustekinumab had neutralizing antibodies. In Crohn’s disease and ulcerative colitis clinical studies, 2.9% and 4.6% of subjects, respectively, developed antibodies to ustekinumab when treated with STELARA® for approximately one year. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was seen.

**Postmarketing Experience:** The following adverse reactions have been reported during post-approval of STELARA®. 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 STELARA® exposure. Immune system disorders: Serious hypersensitivity reactions (including anaphylaxis and angioedema), other hypersensitivity reactions (including rash and urticaria) [see Warnings and Precautions]. Infections and infestations: Lower respiratory tract infection (including opportunistic fungal infections and tuberculosis) [see Warnings and Precautions]. Neurological disorders: Posterior Reversible Encephalopathy Syndrome (PRES) [see Warnings and Precautions]. Respiratory, thoracic and mediastinal disorders: Interstitial pneumonia, eosinophilic pneumonia and cryptogenic organizing pneumonia [see Warnings and Precautions]. Skin reactions: Pustular psoriasis, erythrodermic psoriasis.

**STELARA® (ustekinumab)**

Infections: In patients with Crohn’s disease, serious or other clinically significant infections included anal abscess, gastroenteritis, and pneumonia. In addition, listeria meningitis and ophthalmic herpetic zoster were reported in one patient each [see Warnings and Precautions].

Malignancies: With up to one year of treatment in the Crohn’s disease clinical studies, 0.2% of STELARA®-treated subjects (0.52 events per hundred patient-years) and 0.2% of placebo-treated subjects (0.58 events per hundred patient-years) developed non-melanoma skin cancer. Malignancies other than non-melanoma skin cancers occurred in 0.2% of STELARA®-treated subjects (0.27 events per hundred patient-years) and in none of the placebo-treated subjects. Hypersensitivity Reactions Including Anaphylaxis: In CD studies, two patients reported hypersensitivity reactions following STELARA® administration. One patient experienced signs and symptoms consistent with anaphylaxis (tightness of the throat, shortness of breath, and flushing) after a single subcutaneous administration (0.1% of patients receiving subcutaneous STELARA®). In addition, one patient experienced signs and symptoms consistent with or related to a hypersensitivity reaction (chest discomfort, flushing, urticaria, and increased body temperature) after the initial intravenous STELARA® dose (0.08% of patients receiving intravenous STELARA®). These patients were treated with oral antihistamines or corticosteroids and in both cases symptoms resolved within an hour. Ulcerative Colitis: The safety of STELARA® was evaluated in two randomized, double-blind, placebo-controlled studies in UC adults (USTECD-1 [induction] and USTECD-2 [induction and maintenance]), and in a postmarketing study involving 960 adult subjects with moderately severe ulcerative colitis [see Clinical Studies (14.5) in Full Prescribing Information]. The overall safety profile of STELARA® in patients with ulcerative colitis was consistent with the safety profile seen across all approved indications. Adverse reactions occurring at a frequency of greater than or equal to 2% in STELARA®-treated subjects and higher than placebo were:

- Diarrhea
- Infection
- Sinusitis
- Upper respiratory tract infection
- Vomiting

**Table 2:** Common adverse reactions through Week 8 in Studies CD-1 and CD-2 occurring in >3% of STELARA®-treated subjects and higher than placebo

<table>
<thead>
<tr>
<th>Reaction</th>
<th>STELARA®</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main single intravenous induction dose</td>
<td>N=470</td>
<td>N=466</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Table 3: Common adverse reactions through Week 44 in Study CD-3 occurring in >3% of STELARA®-treated subjects and higher than placebo

<table>
<thead>
<tr>
<th>Reaction</th>
<th>STELARA®</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 mg subcutaneous maintenance dose every 8 weeks</td>
<td>N=131</td>
<td>N=133</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>8%</td>
<td>11%</td>
</tr>
<tr>
<td>Injection site erythema</td>
<td>0%</td>
<td>5%</td>
</tr>
<tr>
<td>Vaginal candidiasis/mycotic infection</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>2%</td>
<td>4%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>
psoriasis studies the safety of STELARA® in combination with immunosuppressive agents or phototherapy has not been evaluated [see Warnings and Precautions]. In psoriatic arthritis studies, concomitant use did not appear to influence the safety or efficacy of STELARA®. In Crohn's disease and ulcerative colitis induction studies, immunomodulators (6-MP, AZA, MTX) were used concomitantly in approximately 30% of subjects, and corticosteroids were used concomitantly in approximately 40% and 50% of Crohn's disease and ulcerative colitis subjects, respectively. Use of these concomitant therapies did not appear to influence the overall safety or efficacy of STELARA®. CYP450 Substrates: The formation of CYP450 substrates can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNF-α, IFN) during chronic inflammation. Thus, STELARA®, an antagonist of IL-12 and IL-23, could normalize the formation of CYP450 enzymes. Upon initiation of STELARA® in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, monitoring for therapeutic effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) should be considered and the individual dose of the drug adjusted as needed [see Clinical Pharmacology (12.3) in Full Prescribing Information]. Allergen Immunotherapy: STELARA® has not been evaluated in patients who have undergone allergen immunotherapy. STELARA® may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy. STELARA®, an antagonist of IL-12 and IL-23, could normalize the formation of CYP450 enzymes. Upon initiation of STELARA® in pregnant women are insufficient to inform a drug associated risk [see Data]. In animal reproductive and developmental toxicity studies, no adverse developmental effects were observed in mice prenatally dosed with ustekinumab to pregnant monkeys at exposures greater than 100 times the human exposure at the maximum recommended human subcutaneous dose (MRHD). The background risk of major birth defects and miscarriage for the indicated population(s) are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage of clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Data: Human Data: Limited data on the use of STELARA® in pregnant women are insufficient to inform a drug associated risk. Animal Data: Ustekinumab was tested in two embryo-fetal development toxicity studies in cynomolgus monkeys. No teratogenic or other adverse developmental effects were observed in fetuses from pregnant monkeys that were administered ustekinumab subcutaneously twice weekly or intravenously weekly during the period of organogenesis. Serum concentrations of ustekinumab in pregnant monkeys were greater than 100 times the serum concentration in patients treated subcutaneously with 90 mg of ustekinumab weekly for 4 weeks. In a combined embryo-fetal development and pre- and postnatal development toxicity study, pregnant cynomolgus monkeys were administered subcutaneous doses of ustekinumab twice weekly at exposures greater than 100 times the human subcutaneous exposure from the beginning of organogenesis to Day 33 after delivery. Neontal deaths occurred in the offspring of one monkey administered ustekinumab at 22.5 mg/kg and one monkey dosed at 45 mg/kg. No ustekinumab-related effects on functional, morphological, or immunological development were observed in the neonates from birth through six months of age. Lactation: Risk Summary: There are no data on the presence of ustekinumab in human milk, the effects on the breastfed infant, or the effects on milk production. Ustekinumab was present in the milk of lactating monkeys administered ustekinumab. Due to species-specific differences in lactation physiology, animal data may not reliably predict drug levels in human milk. Maternal IgG is known to be present in human milk. Published data suggest that the systemic exposure to a breastfed infant is expected to be low because ustekinumab is a large molecule and is degraded in the gastrointestinal tract. However, if ustekinumab is transferred into human milk the effects of local exposure in the gastrointestinal tract are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for STELARA® and any potential adverse effects on the breastfed child from STELARA® or from the underlying maternal condition. Pediatric Use: The safety and effectiveness of STELARA® have been established in pediatric patients 6 to 17 years old with moderate to severe plaque psoriasis. Use of STELARA® in adolescents is supported by evidence from a multicenter, randomized, 80-week trial (Ps STUDY 3) that included a 12-week, double-blind, placebo-controlled, parallel-group portion, in 110 pediatric subjects 12 years and older [see Adverse Reactions, Clinical Studies (14.2) in Full Prescribing Information]. Use of STELARA® in children 6 to 11 years with moderate to severe plaque psoriasis is supported by evidence from an open-label, single-arm, efficacy, safety and pharmacokinetics study (Ps STUDY 4) in 44 subjects [see Adverse Reactions, Pharmacokinetics (12.3) in Full Prescribing Information]. The safety and effectiveness of STELARA® for pediatric patients less than 6 years of age with psoriasis have not been established. The safety and effectiveness of STELARA® have not been established in pediatric patients with psoriatic arthritis, Crohn's disease or ulcerative colitis. Geriatric Use: Of the 6798 patients exposed to STELARA®, a total of 340 were 65 years or older (183 patients with psoriasis, 65 patients with psoriatic arthritis, 58 patients with Crohn's disease and 34 patients with ulcerative colitis), and 40 patients were 75 years or older. Although no overall differences in safety or efficacy were observed between older and younger patients, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients. OVERDOSAGE: Single doses up to 6 mg/kg intravenously have been administered in clinical studies without dose-limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately. PATIENT COUNSELING INFORMATION: Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide and Instructions for Use). Infections: Inform patients that STELARA® may lower the ability of their immune system to fight infections and to contact their healthcare provider immediately if they develop any signs or symptoms of infection [see Warnings and Precautions]. Malignancies: Inform patients of the risk of developing malignancies while receiving STELARA® [see Warnings and Precautions]. Inform patients to seek immediate medical attention if they experience any signs or symptoms of serious hypersensitivity reactions and discontinue STELARA® [see Warnings and Precautions]. Inform patients the needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex [see Dosage and Administration (2.4) in Full Prescribing Information]. Posterior Reversible Encephalopathy Syndrome (PRES): Inform patients to immediately contact their healthcare provider if they experience signs and symptoms of PRES (which may include headache, seizures, confusion, or visual disturbances) [see Warnings and Precautions]. Immunizations: Inform patients that STELARA® can interfere with the usual response to immunizations and that they should avoid live vaccines [see Warnings and Precautions]. Administration: Instruct patients to follow sharps disposal recommendations, as described in the Instructions for Use. REFERENCES: Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Incidence - US 1973-2007 Counties, National Cancer Institute, DCCPS, Surveillance Research Program, Surveillance Systems Branch, released April 2010, based on the November 2009 submission. Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403 and at Cilag AG, Schaffhausen, Switzerland Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1894 at Cilag AG, Schaffhausen, Switzerland © 2012, 2016, 2019 Janssen Pharmaceutical Companies cp-125602v4
**Continued from Page 39**

**Evaluating severity and extent of IBD**

**Feuerstein:** Inflammatory bowel disease is a chronic immune-mediated disease process that can be progressive and cause relapsing flares. What are the common clinical manifestations of ulcerative colitis based on disease location and severity? What objective ways do you assess the disease activity?

**Ungaro:** In ulcerative colitis, the most prominent symptoms typically are rectal bleeding, diarrhea and increased frequency of bowel movements. Symptoms can range from just blood in the stool and a few increased bowel movements per day with milder disease to patients who are going to the bathroom 10-plus times a day. They’re having abdominal pain and more systemic symptoms like fevers, chills and fatigue. There are other common symptoms particularly in patients who have limited disease or where the rectum is very inflamed. Patients with proctitis can often present primarily with a lot of urgency or with tenesmus — a sensation of incomplete evacuation. Symptoms can run the gamut, but typically all have bloody diarrhea and increased stool frequency.

To evaluate disease severity, we use a combination of subjective and objective metrics. No. 1 is patient symptoms — bowel movement frequency and whether they are seeing blood. We pair that with objective assessments because sometimes the symptoms can be deceiving. So we’re looking not only at blood-in-stool markers of inflammation like CRP, ESR and fecal calprotectin, but also at the endoscopic appearance of the disease, and (we’re) doing a sigmoidoscopy or colonoscopy to measure inflammation severity. It’s important to note if someone has milder disease and just some erythema versus a more severe case where they could have deep serpiginous or punched-out ulcerations.

**Feuerstein:** What are the most common extraintestinal manifestations of inflammatory bowel disease?

**Hanauer:** The most common are joint involvement, skin involvement and eye involvement. They can occur in up to 30% of patients who have either ulcerative colitis or Crohn’s disease. We tend to distinguish two types of extraintestinal manifestations. (The) most common are those associated with active inflammation including arthritis or arthralgias that typically involve the larger joints, which may precede or occur concomitantly with the intestinal inflammation and symptoms.

A second type of arthritic manifestation, central arthritis, involves the spine and includes ankylosing spondylitis and sacroiliitis. In contrast with peripheral arthritis, these are associated with a genetic type of HLA-B27 and more common in patients who are HLA-B27 positive. In the eye, iritis or uveitis is another HLA-B27-associated inflammation. Scleritis can occur associated with active inflammation. They’re quite diverse, and we usually engage a rheumatologist, an ophthalmologist or sometimes a dermatologist to help us with these distinctions.

**Sands:** Fatigue is very common in both type of disease and doesn’t necessarily improve with treatment. The classic skin manifestations seen are erythema nodosum or pyoderma gangrenosum, and you may see inflammatory mouth sores. Ileal colonoscopy is very helpful in evaluating the extent and severity of the disease. Cross-sectional imaging is more important, too, because many patients have purely small-bowel disease, so you need more extensive evaluation. Video capsule endoscopy is another way that small-bowel disease can be evaluated, but it is never really a first modality of evaluation.

**CASE STUDY:**

**Diagnostic work-up for a patient with symptoms of IBD**

A 24-year-old woman presents with six months of abdominal pain, a 20-pound weight loss and an increase in bowel movements. She’s having seven nonbloody bowel movements during the day, and often wakes up at night with urgency, having to run to the bathroom again. She has occasional nausea and vomiting. Fasting seems to improve her symptoms.

**Feuerstein:** How would you initially work-up this patient with symptoms suggestive of inflammatory bowel disease, including the type of testing you would order?

**Hanauer:** We’re looking for red-flag symptoms or aspects that would be associated with inflammation, and she certainly has these. She has progressive symptoms associated with weight loss and nocturnal bowel movements, which would be very uncommon in patients who have irritable bowel syndrome. Likewise, the abdominal pain is less likely going to present in celiac disease; in those patients, diarrhea is going to be more common on presentation. The fact that she’s not having bloody bowel movements despite these severe symptoms makes me think against ulcerative colitis and more likely for Crohn’s disease. That would lead to additional diagnostic testing.
Ungaro: It’s always important to have that initial set of stool studies to rule out infection. Because we’re highly suspicious that there’s some inflammatory condition of the bowel, possibly IBD, whether it’s Crohn’s or ulcerative colitis, I’d go for a colonscopy and cross-sectional imaging. I’d probably do MR (magnetic resonance) enterography or CT enterography plus a colonoscopy to get a tissue biopsy, to see the full extent of the disease and to evaluate for any potential complications.

When patients have significant weight loss and other systemic symptoms, like fevers, you want to make sure there are no strictures, fistulas or potential abscesses. A full evaluation would require both the colonoscopy and the MRI. For a single choice, I’d want to go for colonoscopy, where you’re also going to get tissue to cinch that diagnosis.

Feuerstein: What factors would be most important to consider when choosing a therapeutic agent for this patient?

Sands: This patient is fairly sick. Assuming that the diagnosis is indeed Crohn’s disease, you have several options. You’ll want to consider the efficacy and safety, the convenience to the patient and access to the treatment. Hopefully most patients will be insured because many of the treatments we use are of considerable cost. All those factors play a role.

We have many agents now that are effective, work quickly and can work in more severe disease, such as in this patient based on her weight loss and remarkable symptoms. These include broad categories of biologic agents such as anti-TNF (tumor necrosis factor) antibodies; other newer biologic agents such as vedolizumab and ustekinumab; and older agents such as methotrexate, which has a steroid-sparing role, and mercaptopurine and azathioprine, which are thiopurine immunomodulators. We have moved away from those because they don’t have wonderful safety profiles, but they’re adequate safety profiles, and we used them for many years. But the biologic agents prove to be probably safer.

Feuerstein: Would you review the two newest therapeutic agents — the JAK (Janus kinase) inhibitor tofacitinib and the S1P receptor modulator ozanimod — and how they might be integrated into treatment plans?

Sands: Both tofacitinib and ozanimod, in contrast with those just mentioned, are oral agents. They’re small-molecule agents. At this point, they’re approved for only ulcerative colitis within the realm of IBD.

Tofacitinib is a ... pan-JAK inhibitor, which inhibits downstream inflammatory responses within inflammatory cells. It is effective in ulcerative colitis. But it’s positioned as a second-line agent for use after patients have failed anti-TNF agents.

Tofacitinib recently has added a black box warning for venous thromboembolism and increased mortality. This is based on data from the rheumatoid arthritis population (that have) been generalized to use in ulcerative colitis. Tofacitinib is effective but is somewhat less effective after a patient has failed an anti-TNF, which paradoxically is exactly the patient we would use it for.

Ozanimod is the newest agent. It had already been on the market for treatment of multiple sclerosis. It’s an S1P receptor agonist, or sphingosine-1-phosphate receptor agonist, which sequesters lymphocytes in lymph nodes and keeps them out of circulation. It’s another approach to targeting migration of inflammatory cells and lymphocytes into the gut mucosa, but in this case, they are trapped, not killed. Consequently, you can expect to see lymphopenia. Interestingly, you don’t see much increased risk of infections. You see a slight uptick in herpes zoster but not much else of note.

There are some other safety issues with ozanimod. It’s given in up-titrated dosing because it has cardiac conduction effects. There are also rare cases of liver function abnormalities. I mentioned the lymphopenia. It can also cause macular edema and rare cases of pulmonary function abnormalities. You don’t necessarily have to monitor for that, but be aware of it. Ozanimod is effective in ulcerative colitis and provides another oral option for treatment.”
Things You Should Know About Managing Alpha-1 Antitrypsin Deficiency

Release Date: December 1, 2021
Expiration Date: December 1, 2022

Learning Objectives

Upon successful completion of this activity, you should be better prepared to:
• Perform diagnosis of patients with suspected α-1 antitrypsin deficiency (AATD) using recommended laboratory tests and clinical assessments
• Apply knowledge of recommended diagnostic assessments and management strategies to patient scenarios

Acknowledgment of Commercial Support

This activity is supported by educational grants from Grifols and Takeda Pharmaceuticals U.S.A., Inc.

Off-Label Disclosure/Disclaimer

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The staff of PER® have no relevant financial relationships with commercial interests to disclose.

Instructions for Participation

1. Read this activity in its entirety.
2. Go to gotoper.com/go/chest21a1at-post to access and complete the post-test.
3. Answer the evaluation questions.

To learn more about this topic, including information on identifying and treating patients with AATD, go to gotoper.com/online-cme-activities/cpc/cpc21osdam
An estimated 48 million individuals worldwide have an elevated risk of α₁-antitrypsin deficiency (AATD), including 1 of every 3000 to 6000 North Americans. This condition, which is inherited in an autosomal codominant pattern, results in reduced amounts of the protease inhibitor AAT. Mainly produced by hepatocytes—with additional production in lung epithelial cells, neutrophils, and macrophages—AAT inhibits neutrophil elastase and other proteases in the lungs. AATD can be associated with disease in the lungs, liver and beyond. Here are 3 things you should know about the management of AATD.

1. If you see COPD, think about AATD.
Lung disease resulting from AATD typically presents in individuals 30 years of age or older, with nonspecific respiratory symptoms such as cough, dyspnea and wheezing. AATD can result in damage to alveolar tissue and eventual emphysema, and up to 5% of individuals with chronic obstructive pulmonary disease (COPD) have AATD.

2. Testing goes beyond measuring AAT levels
Typically, screening and diagnosis of AATD begins with measurement of serum AAT; genetic testing for AAT alleles can be performed simultaneously, and buccal swabs are now available for genetic testing. If the patient has AATD, identifying the genotype is important for detecting alleles associated with variable levels of AAT or near-normal levels with abnormal function, as well as for assessing the individual’s risk of liver disease.

AAT is encoded by the SERPINA1 gene on chromosome 14, and more than 120 genetic variants have been discovered. The most common deficiency alleles are PI*S and PI*Z. The following combinations of normal and deficiency alleles result in a range of serum AAT levels:

<table>
<thead>
<tr>
<th>AAT LEVELS</th>
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<tbody>
<tr>
<td>PI*MM</td>
<td>100%, or greater than 20 µmol/L</td>
</tr>
<tr>
<td>PI*MS</td>
<td>80%</td>
</tr>
<tr>
<td>PI*SS</td>
<td>60%, or 14 to 20 µmol/L</td>
</tr>
<tr>
<td>PI*MZ</td>
<td>55%</td>
</tr>
<tr>
<td>PI*SZ</td>
<td>40%</td>
</tr>
<tr>
<td>PI*ZZ</td>
<td>15%, or 5 to 6 µmol/L</td>
</tr>
</tbody>
</table>

In addition, null variants are associated with severe AATD.

The Alpha-1 Foundation guidelines also recommend initial complete lung function testing in patients diagnosed with AATD and, in those who are symptomatic or have abnormal pulmonary function testing, a baseline CT chest scan.

3. AATD treatment addresses deficiency and lung symptoms
The only disease-specific therapy for AATD is intravenous (IV) augmentation with AAT protein derived from pooled human plasma. The therapy is indicated for patients with serum AAT levels below 11 µmol/L—the estimated protective threshold value—and emphysema with
A decline in lung function. Augmentation therapy, which is typically given weekly for the lifetime of the patient, only addresses lung disease in AATD but not hepatic disease or other sequelae. 

Currently, 4 augmentation products are available in the United States, which contain different concentrations of AAT but have relatively similar storage and administration considerations. 

The Alpha-1 Foundation guidelines recommend augmentation therapy for patients with AATD who have forced expiratory volume in the first second of expiration (FEV₁) of 30% to 65% predicted or FEV₁ less than 30% predicted. For patients with FEV₁ greater than 65% predicted, the foundation recommends discussing potential benefits of the therapy vs cost and lack of evidence with the patient. The guidelines do not recommend the therapy for patients with lung disease who continue to smoke, those with bronchiectasis without airflow obstruction, or individuals with the MZ genotype and COPD.

The RAPID trial compared IV augmentation therapy (60 mg/kg weekly) versus placebo for 24 months. Patients (n = 180) were adults with AATD-related emphysema with serum AAT levels of 11 µmol/L or lower and FEV₁ of 35% to 70% predicted. The primary outcome was annual rate of decrease in lung density calculated at total lung capacity (TLC) and at functional residual capacity (FRC) combined and separately. Lung density changes on CT served as a surrogate for changes in emphysema progression. 

For the combination of TLC and FRC, the augmentation group showed a nonsignificant 29% reduction in rate of lung density loss compared with the placebo group. At TLC alone, the treatment group had a significant 34% reduction in rate of lung density loss compared with placebo, but this difference was not significant at FRC alone. Adverse events were similar between the groups.

Management of chronic AATD-associated lung disease and acute exacerbations is generally the same as for patients with COPD, including use of bronchodilators and inhaled corticosteroids. The GOLD guidelines call for antibiotics for COPD exacerbations only in patients on mechanical ventilation and those with increased dyspnea, sputum volume, and sputum purulence (or 2 of these symptoms if increased sputum purulence is one of them).

Avoiding smoking is crucial for people with AATD

Smoking cessation for patients who smoke is critical, given that smoking raises the risk of lung disease and faster decline in lung function. Avoiding occupational dust and fumes is also advisable.

KEY REFERENCES
For a full list of references go to gotoper.com/go/chest21a1at-post
POST-TEST QUESTIONS

1. Your patient is a 32-year-old man who has a history of longstanding dyspnea, intermittent wheezing, and multiple episodes of pneumonia and “bronchitis” every year. He has been on various inhaled and oral therapies for his lung disease, with varying success. Which of the following would be the best next step in his management?
   
   A. CBC with differential and platelet count  
   B. Buccal smear for SERPINA1 mutation testing  
   C. Complete lung function testing, including forced expiratory volume in the first second of expiration (FEV₁) and total lung capacity  
   D. High-resolution computerized tomography of the thorax

2. The RAPID trial was a multicenter, double-blind, randomized, parallel-group, placebo-controlled trial of α₁-proteinase inhibitor treatment in patients with α₁-antitrypsin deficiency (AATD). Subjects had an FEV₁ of 35% to 70% of predicted. Which of the following was true of the patients in this trial?
   
   A. Treatment-related adverse events were almost twice as high in the treatment group compared with the placebo group  
   B. The results of the patients in the treatment group contrasted with the results of earlier studies done without using lung density measurements by CT scan.  
   C. The annual rate of lung density loss at total lung capacity alone was significantly less in patients in the treatment group compared with the placebo group

3. Optimal management of patients with AATD includes all of the following EXCEPT which intervention?
   
   A. Inhaled bronchodilators as indicated  
   B. Preventive vaccinations against hepatitis A and B  
   C. Pulmonary rehabilitation  
   D. Antibiotics for all exacerbations of chronic obstructive pulmonary disease symptoms

To learn more about this topic, including information on identifying and treating patients with AATD, go to gotoper.com/online-cme-activities/cpc/cpc21osdam
Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

### Choosing the Right Sized Unit

1. **Determine the maximum number of doses of particular vaccines you will store per month**

2. **Match your maximum doses with the minimum cubic feet of storage needed for your vaccine**

#### Refrigerators

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Height</th>
<th>Width</th>
<th>Depth</th>
<th>Door</th>
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<td>1 cu.ft.</td>
<td>22.5&quot;</td>
<td>14.8&quot;</td>
<td>19.2&quot;</td>
<td>Glass</td>
<td>717.00</td>
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<tr>
<td>2 cu.ft.</td>
<td>23.5&quot;</td>
<td>15.5&quot;</td>
<td>20&quot;</td>
<td>Glass</td>
<td>839.00</td>
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<tr>
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<td>6 cu.ft.</td>
<td>30.25&quot;</td>
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<td>23&quot;</td>
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<td>1,100.00</td>
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<td>Glass</td>
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<tr>
<td>12 cu.ft.</td>
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<td>15 cu.ft.</td>
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<td>25&quot;</td>
<td>Glass</td>
<td>2,390.00</td>
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#### Freezers

<table>
<thead>
<tr>
<th>Capacity</th>
<th>Height</th>
<th>Width</th>
<th>Depth</th>
<th>Door</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 cu.ft.</td>
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</table>

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<table>
<thead>
<tr>
<th>Medical Equipment</th>
<th>Price</th>
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</thead>
<tbody>
<tr>
<td>Bionet CardiTouch 3000</td>
<td>$1,550.00</td>
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<tr>
<td>MobiPok 8200</td>
<td>$2,530.00</td>
</tr>
<tr>
<td>Welch Allyn CP150 w/ Interp.</td>
<td>$2,946.00</td>
</tr>
<tr>
<td>Burdick ELI 280</td>
<td>$4,294.00</td>
</tr>
<tr>
<td>Schiller FT-1</td>
<td>$2,530.00</td>
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</tbody>
</table>

**Tools for Increased Reimbursement & Office Efficiency at Discount Prices**

<table>
<thead>
<tr>
<th>Equipment Description</th>
<th>Price</th>
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<tbody>
<tr>
<td>Electrocardiogram (ECG)</td>
<td>$1,895.00</td>
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<tr>
<td>Cardiograph (CG)</td>
<td>$2,395.00</td>
</tr>
<tr>
<td>Cardiostress</td>
<td>$2,995.00</td>
</tr>
</tbody>
</table>

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Only $878.00

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PC Based and Direct-to-Printer Asthma 300 USB

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MEDICAL EQUIPMENT

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   - Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
   - Reimburses $170/test using 3 CPT codes
   - Provides a 1 page summary up to a full 24 page comprehensive report

2. SUDOMOTOR TESTING (can be combined with ANS into 1 full system)
   - Takes 3 minutes to analyze a patients’ hands and feet
   - Provides a 1 page summary report
   - Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
   - Reimburses $130/test (national average)

3. NEURO-COGNITIVE TESTING
   - Medicare mandates yearly cognitive assessment
   - Takes 10-15 minutes to prep patient, 20 minutes to test
   - Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
   - Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
   - Each test is processed into a fully-finished, clinically actionable report
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**BRIEF SUMMARY**

**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 (HZ) (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 2 to 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic 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.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX (see Adverse Reactions (6.2)).

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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.

Adults Aged 50 Years and Older

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 (14,660 vaccine doses) 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 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,531 (60%) 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%), followed by Asian (18%), Black (1%), and other racial/ethnic groups (6%); 58% were female.

**Solicited Adverse Reactions:** In Studies 1 and 2, data on solicited local and general adverse reactions 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 and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td>Pain</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,311</td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>9</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>General Adverse Reactions</strong></td>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>9</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>1</td>
</tr>
<tr>
<td>GI</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2</td>
<td>1</td>
<td>1</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, and 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.

The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The local and general adverse reactions seen with SHINGRIX had a median duration of 2 to 3 days.

(continued on next page)
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% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, respectively) compared with Dose 1 (1.4%, 1.4%, 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 51% and 32% of subjects who received SHINGRIX (n = 14,645) or 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 (4% 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 or 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%) or placebo (2.2%) from the first administered dose up to 30 days post-last vaccination. SAEs were reported for 1.01% 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. 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.

**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. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

**Dosing Schedule:** In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. 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 the vaccine.

**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.

**Nervous System Disorders**

Guillain-Barré syndrome.

**Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX**

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

**Risk Summary**

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

**Adults Aged 60 Years and Older**

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions 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).

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SGX:JRNA210071 September 2021
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VERIFY, THEN VACCINATE

THE CDC RECS MAY HELP YOU IDENTIFY PATIENTS FOR VACCINATION

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 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
• In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on 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.


You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

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SGXJRNA210071 September 2021
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- A specialty-trained team of advanced providers, nursing staff and navigators dedicated to our cardiac patients and families, keeping the care team and patient’s local physicians connected.
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- The Fetal Cardiology Program
- The Home Monitoring Program
- The Cardiovascular Genetics Program
- The Adult Congenital Heart Disease (ACHD) Program

Highest rating ★★★★ from the Society of Thoracic Surgeons

To refer a patient to the Riley Heart Center or for more information about the program, visit rileychildrens.org/heartcare

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