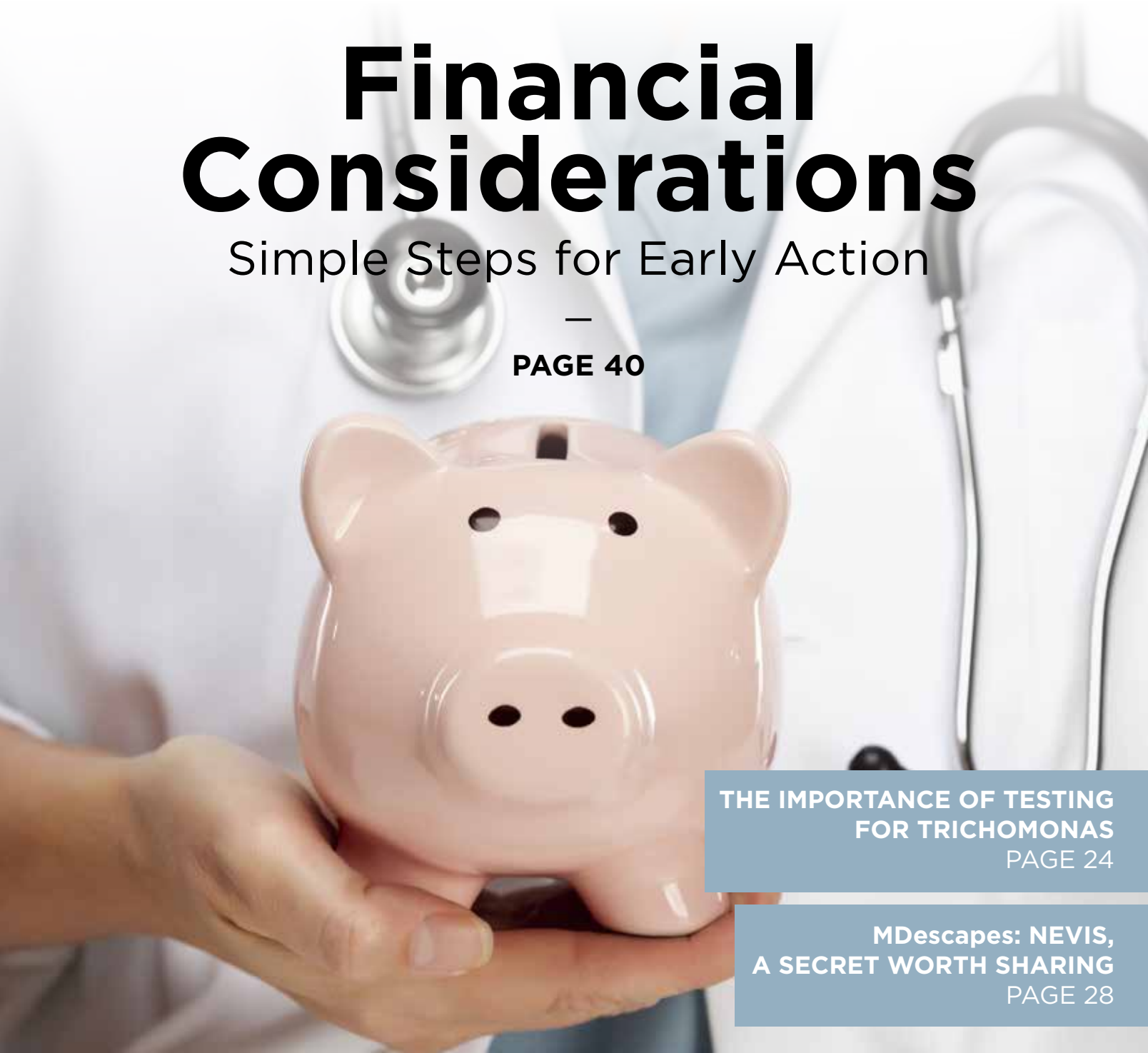
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Physicians office Resource

Resources for You, Your Patients, & Your Practice



Financial Considerations

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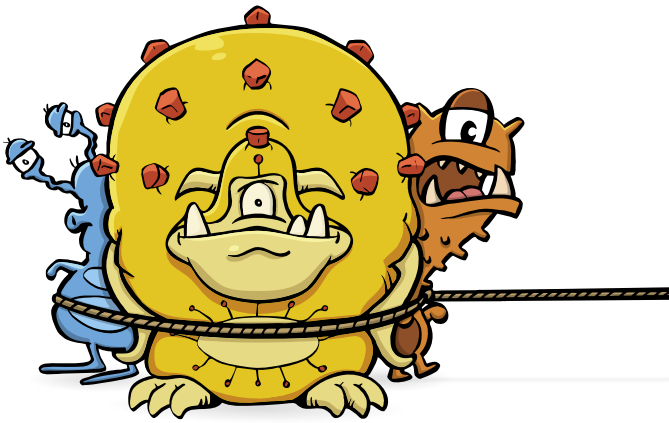
THE IMPORTANCE OF TESTING FOR TRICHOMONAS
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MDescapes: NEVIS, A SECRET WORTH SHARING
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PIONEERING DIAGNOSTICS

BIOMÉRIEUX

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



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

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

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

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



1300

BioFire RP2.1-EZ Panel (EUA)

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

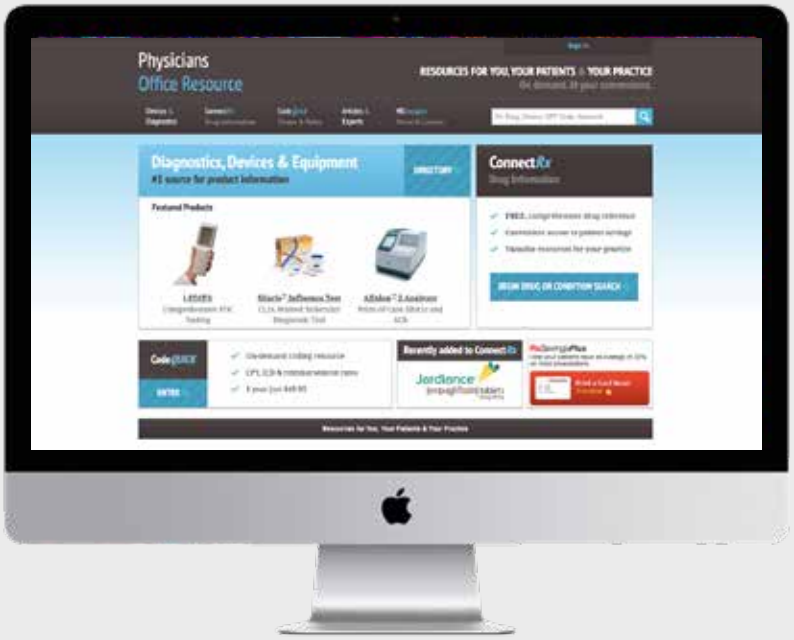
SARS-CoV-2 98.0% sensitivity and 100% specificity (archived specimens)[5]

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

BIOFIRE®

1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of invitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. 2. http://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm 3. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration. 4. Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel. 5. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission 6. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.

BFR0001-0517-02



Getting the most from this guide

There are two simple ways to request information about the products and services found in Physicians Office Resource.

1. Go to www.PhysiciansOfficeResource.com and enter the four-digit reference number found next to the product or service into the search field, then request additional information, schedule a demo, or speak with a sales agent all with just a simple click of a button.

2. Find the Business Reply Card in this issue, circle the desired reference numbers, complete the form, and drop into any USPS mailbox. A representative will contact you as quickly as possible to answer your questions.

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Financial Considerations Unique to U.S. Physicians

Simple Steps for Early Action

For the average U.S. household, everyday living is getting pricey. Childcare, food, energy, transportation, and housing costs are all rising. Among U.S. physicians and healthcare professionals, personal financial matters may make things tougher given high educational debt-loads, capped income levels during residency years, and unique insurance needs.

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THE IMPORTANCE OF TESTING FOR TRICHOMONAS

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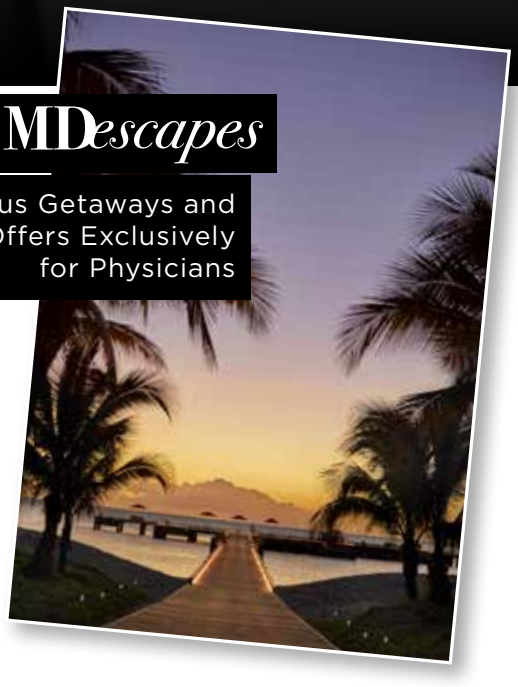
Estimated global incidence of Trichomonas vaginalis compared to three other curable STIs (Chlamydia trachomatis, Neisseria gonorrhoeae, and syphilis) according to WHO

28

MDescapes: NEVIS, A SECRET WORTH SHARING

—

It's like a secret that nobody knows. You mention in passing that you've just been to paradise, and it's an island called Nevis in the West Indies. Chances are they've never heard of it.





Now there's an easy and effective way to screen for osteoporosis.

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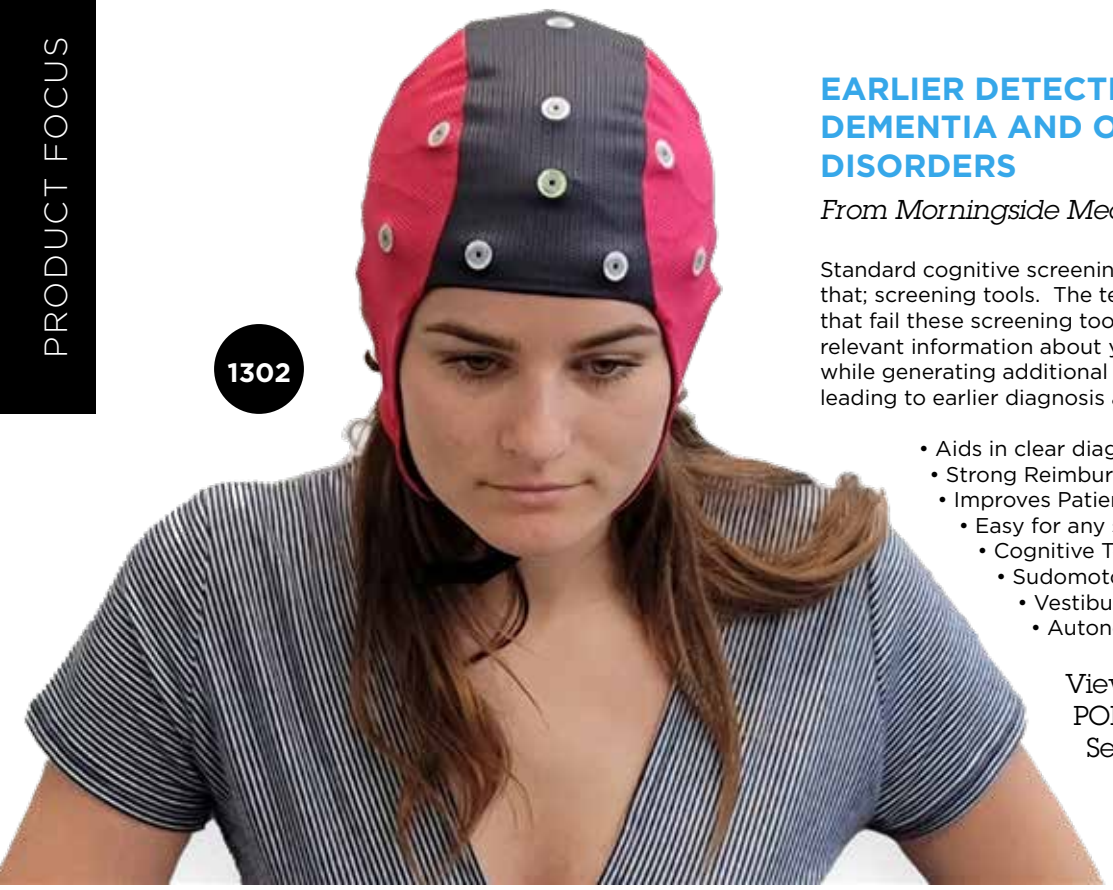
Bindex is the world's first evidence-based, point-of-care osteoporosis diagnostics device that provides results comparable with DXA. Portable, hand-held and lightweight, Bindex scans in seconds and at a fraction of the cost allowing you to quickly provide much-needed osteoporosis diagnostics for your at-risk patients.

NOW YOU CAN TRIAL BINDEX AT NO COST.

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BINDEX

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1302

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From Morningside Medical

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- Strong Reimbursement
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Schiller FT-1: $2,530.00
Burdick ELI 280: $4,294.00
Welch Allyn CP150 w/ Interp: $3,645.00

ADView 2 Vital Signs Monitor



1305

The Adview 2 is still the only truly modular diagnostic station that grows with your needs. Start with blood pressure and choose temperature or pulse oximetry option at the time of purchase. **Starting at $676.00**

EMR-Compatible PC-Based Diagnostics



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Cardio Resting EKG: $1,895.00
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PC Based and Direct-to-Printer Astra 300 USB* $898.00
*Touch Screen Display

Lifeline AED



1309

Only $1,245.00
Gold Standard AED

Pharmacy/VaccineRefrigerators & Freezers (Meets CDC and VFC guidlines)



1310

Refrigerators
8 cu ft Refrigerator w/ Solid Door (ARS8PV): $1,497.60
15 cu ft Refrigerator w/ Solid Door (ARS15PV): $2,294.50

Freezers
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1311

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with Specula Dispenser: $866.00

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Family Practice Exam Table



A durable, reliable, patient-friendly exam table for any office. Many base and upholstery color combinations.

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Only $824.00

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Our Price:
$299.00

CLIA Waived COVID-19 Test

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CareStart SARS-CoV-2 Rapid Antigen Test (20 Tests)
As an intended point-of-care (POC) designated test with a 10 min processing time, CareStart COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale. Rapid results within 10 minutes. Identify acute infection with 88.4% sensitivity and 100% specificty. FDA & EUA approved!



Reimbursement:
National Average
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Boost Your Revenue!

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Neuro-Cognitive Testing for Primary Care Physicians
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BONE HEALTH



1317

WHY BINDEX® IS A GAME-CHANGER IN OSTEOPOROSIS DIAGNOSTICS.

From Bindex Medical

Comparable to DXA
Extensive clinical research has proven Bindex to be 90% accurate in detecting osteoporosis. It can replace nearly 70% of DXA scans for patients with suspected osteoporosis.

Fast and effective
Using safe pulse-echo ultrasound to measure cortical bone thickness, Bindex analyzes bone density in just seconds.

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Lightweight and pocket-sized, Bindex allows patients to receive on-the-spot bone density scans in doctors' offices, hospitals and clinics and at home.

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CHEMISTRY ANALYZERS

EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Abbott Point of Care

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For intended use and complete product information, visit pointof-care.abbott.

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1318



1319

FULL COMPLEMENT OF CLIA-WAIVED BLOOD CHEMISTRY TESTS PICCOLO XPRESS® CHEMISTRY ANALYZER

From Abbott Point of Care

The Piccolo Xpress Chemistry Analyzer provides physician offices with lab-accurate results for a broad range of CLIA-waived general chemistry tests, including metabolic panels, lipids, live, and kidney function, and more with just 100 microliters of blood. Easy to use, the PIccolo Xpress provides results during a patient's visit, accelerating treatment decisions, increasing efficiency, and supporting patient satisfaction. Automated quality control on every test helps ensure accuracy.

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Abbott

TRANSFORM PATIENT SATISFACTION AND PRACTICE EFFICIENCY.



1320



i-STAT®

COMPREHENSIVE CLIA Waived MENU AVAILABLE



piccolo xpress chemistry analyzer

1321

CLIA Waived Tests: CMP, BMP, Lipid Panel, Lipid Panel Plus, General Chemistry, Kidney Check, Renal Panel, MetLyte 8 and Electrolytes

Fast—Results in minutes, accelerating patient care decisions.

Accurate—Lab-accurate results for a wide range of tests.*

Versatile—Comprehensive CLIA-waived menu available.

Simple—Intuitive function to improve operational efficiency.

Convenient—Have test results during office visit, increasing patient satisfaction.

To learn more, contact your Abbott Point of Care representative at 888-893-0335, your distribution representative, or visit www.pointofcare.abbott

*2016 Proficiency Testing Results, American Proficiency Institute, www.api-pt.com [*Piccolo Xpress*]. See cartridge information at www.pointofcare.abbott [*i-STAT*].

***i-STAT* Part No:** 04J60-20 Waived Kit, 04J48-50 Moderately Complex Kit, 06F20-20 Waived Analyzer, 04P75-03 Moderately Complex Analyzer
***Piccolo Xpress* Part No:** 07P05-50 *Piccolo Xpress* with 3YR Serv, 07P05-51 *Piccolo Xpress* with 5YR Serv

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Abaxis 888-3355 Rev A

CHEMISTRY ANALYZERS



PENTRA C400 CHEMISTRY ANALYZER

From HORIBA Medical

One benchtop, not a whole lab! No water system, drain or special electrical connected required to operate the Pentra C400 chemistry analyzer. Now you can have the power of a floor model analyzer on the benchtop! The Pentra C400 chemistry system processes up to 420 tests/hr including ISEs and offers routine metabolic assays, TDMs, DAUs and Adulterants, HbA1c and Vitamin D tests. With 40 open channels, you can add much more for a complete menu to meet your practice needs.

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ENVOY500+ DELIVERING PROVEN RESULTS IN CLINICAL CHEMISTRY

From EliTech

The fully automated Envoy500+ is designed to deliver the performance of a large floor model analyzer but provides the cost efficiency of a benchtop analyzer (TPH approx. 490). It enables accurate treatment decisions sooner. Envoy500+ delivers savings the laboratory requires with the following features positive sample and reagent identification, clot detection, liquid level sensing, dry ISE module, reusable glass cuvettes, and many more.

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COVID-19 TESTING



WHY COMPROMISE? FAST AND RELIABLE RESULTS ARE NOW DELIVERED AT THE POINT OF CARE.

From LumiraDx

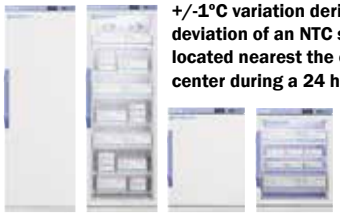
Introducing the next generation in point-of-care diagnostics. With a growing menu of tests, LumiraDx uses a simple process that allows for more time with your patients by using microfluidic technology that delivers results in minutes. Learn more about rapid COVID-19 diagnostic solutions for your physician office at LumiraDx.com.

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+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the champer geometric center during a 24 hour test period

1325

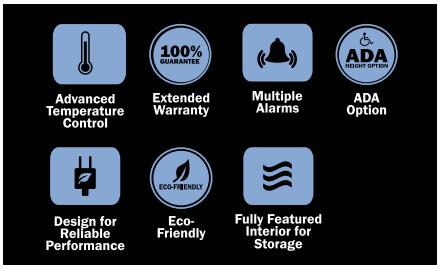
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Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

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- Intelligent microprocessor digital temperature controller
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- Open door and high/low temperature alarms
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Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	**936.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**949.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**1,059.50**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**1,072.50**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**1,180.40**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,193.40**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,497.60**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,510.60**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**2,002.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**2,015.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**2,294.50**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**2,307.50**

models with data loggers are available

Pharma-Lab Refrigerators

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ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**3,113.50**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,413.50**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,771.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**3,178.50**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**5,063.50**

visit www.medicaldevicedepot.com for all product information and options

Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator: Add the number of doses on hand (current inventory) from your last order form.

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

For product application suggestions or recommendations please feel free to contact our product specialists to discuss your options at:

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BIOFIRE® RESPIRATORY 2.1-EZ (RP2.1-EZ)1 PANEL (EUA)1

From BioFire

SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. In your clinic, you can test for 19 common respiratory pathogens, including SARS- CoV-2, with the BioFire RP2.1-EZ Panel (EUA)[1]—now available under an FDA Emergency Use Authorization. Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects.

1. This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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CARESTART™ COVID-19 ANTIGEN TEST

From Mercedes Scientific®

This point-of-care (POC) designated test is one of the top-used amongst our customers.

Features/Benefits:
- CLIA WAIVED
- Results within 15 minutes
- Anterior nasal swab specimen collection
- Detects SARS-CoV-2 nucleocapsid protein antigen
- 87.2% sensitivity and 100% specificity

This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

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LumiraDx™

Why compromise?

Immediacy now comes with accuracy.



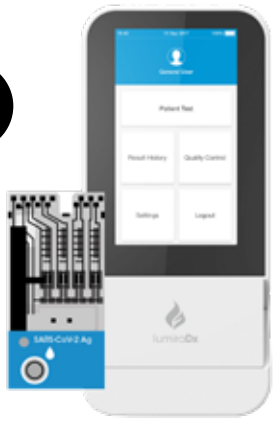
1329

LumiraDx's microfluidic technology provides speed without compromising sensitivity at the point of care.

lumiradx.com

The LumiraDx SARS-CoV-2 Ag Test and the LumiraDx SARS-CoV-2 Ab Test have not been cleared or approved by FDA, but have been authorized for emergency use by FDA under an EUA for use by authorized laboratories. The LumiraDx SARS-CoV-2 Ag Test has been authorized only for the detection of SARS-CoV-2 nucleocapsid protein. The LumiraDx SARS-CoV-2 Ab Test has been authorized only for detecting the presence of total antibodies to SARS-CoV-2. They have not been authorized for use to detect any other viruses or pathogens. The emergency use of these Tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic Tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

S-COM-ART 01806 R1



1330

WHY COMPROMISE? FAST AND RELIABLE RESULTS ARE NOW DELIVERED AT THE POINT OF CARE.

From LumiraDx

Introducing the next generation in point-of-care diagnostics. With a growing menu of tests, LumiraDx uses a simple process that allows for more time with your patients by using microfluidic technology that delivers results in minutes. Learn more about rapid COVID-19 diagnostic solutions for your physician office at LumiraDx.com.

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BIOFIRE® FILMARRAY® TORCH

From BioFire

The BioFire® FilmArray® Torch is a fully integrated, random, and continuous access system designed to meet your laboratory's syndromic infectious disease testing needs. The BioFire Torch offers a radically reduced benchtop footprint, saving precious space in the lab, and its scalability meets high throughput demands. BioFire® FilmArray® Link Software automatically uploads patient results. Fully compatible with all CLIA Moderate BioFire® FilmArray® Panels, the BioFire Torch helps you maximize efficiency and productivity.

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1331



1332

ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing 1333

- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
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- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing 1334

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- Takes less than 10 minutes to perform, software provides verbal cues
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3 SudoMotor Testing 1335

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For your patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (CCA) with an FGFR2 fusion or rearrangement

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FGFR, fibroblast growth factor receptor.

INDICATIONS AND USAGE

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

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

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

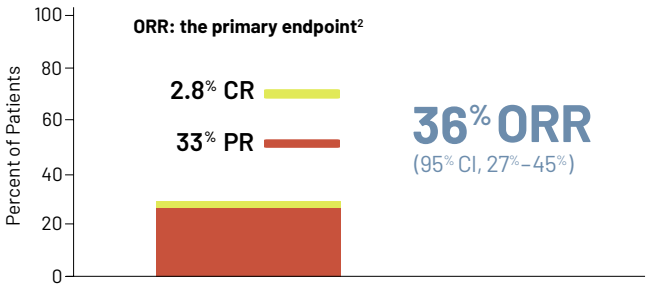
Patients receiving PEMAZYRE achieved durable responses

Median DoR was **9.1** months[1,‡]

Patients with DoR:

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

Clinical response rates of PEMAZYRE[1]



Efficacy evaluable population (N=107)

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

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

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

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

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

Molecular profiling is necessary to detect FGFR2 fusions or rearrangements

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

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

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IMPORTANT SAFETY INFORMATION

Ocular Toxicity

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

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

continued

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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

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

Hyperphosphatemia and Soft Tissue Mineralization

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

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

Embryo-Fetal Toxicity

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

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

Adverse Reactions

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

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

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

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

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

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

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

Drug Interactions

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

Special Populations

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

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

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

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

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

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

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

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

Table 1 continued above.

Table 1 continued.

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

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

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

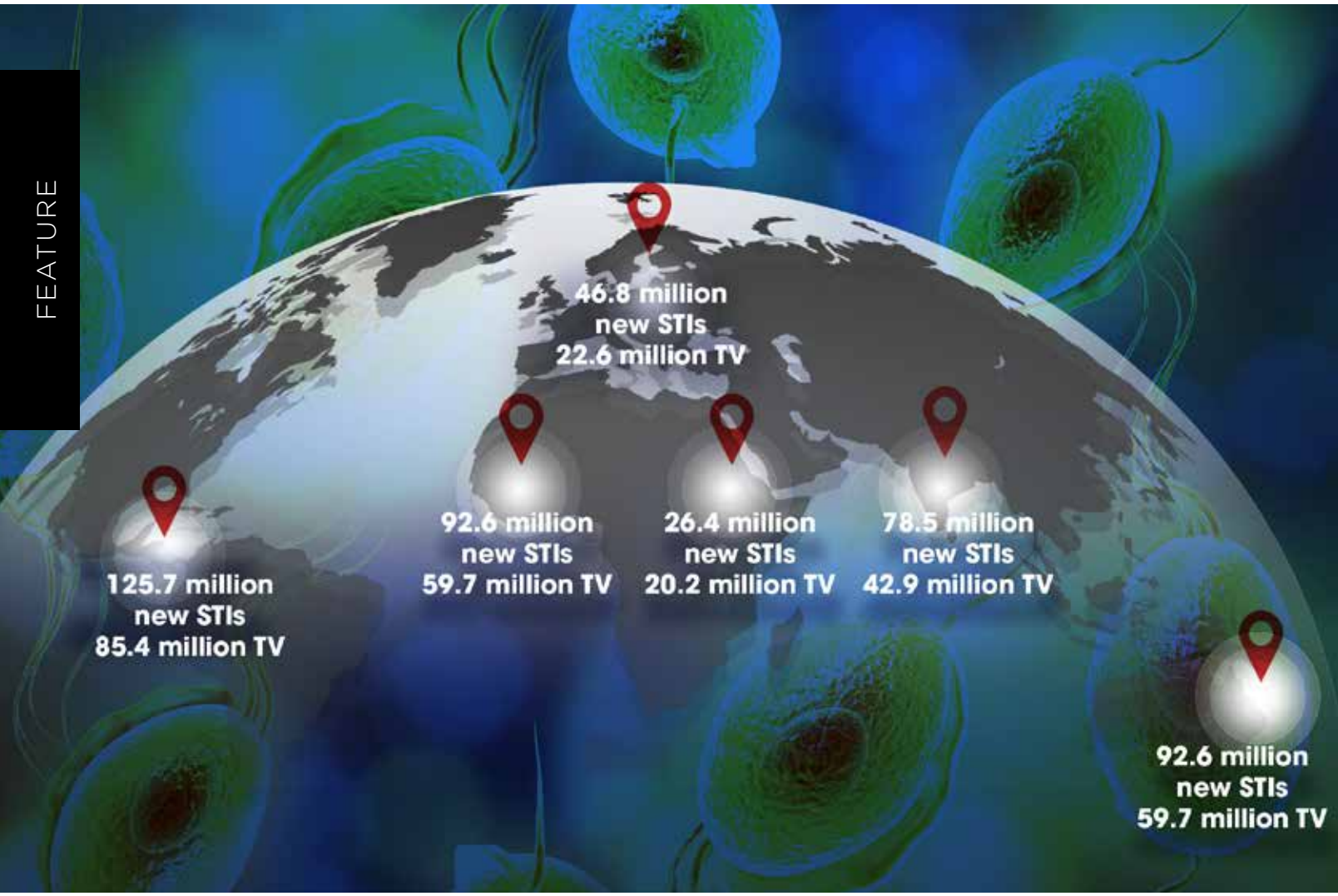
Table 2: Select Laboratory Abnormalities (≥ 10%) Worsening from Baseline in Patients Receiving PEMAZYRE in FIGHT-202

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

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

Increased Creatinine Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **DRUG INTERACTIONS Effect of Other Drugs on PEMAZYRE** Strong and Moderate CYP3A Inducers Concomitant use of PEMAZYRE with a strong or moderate CYP3A inducer decreases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may reduce the efficacy of PEMAZYRE. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE. Strong and Moderate CYP3A Inhibitors Concomitant use of a strong or moderate CYP3A inhibitor with PEMAZYRE increases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may increase the incidence and severity of adverse reactions. Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce PEMAZYRE dosage if concomitant use of strong and moderate CYP3A inhibitors cannot be avoided *[see Dosage and Administration (2.4) in Full Prescribing Information]*. **USE IN SPECIFIC POPULATIONS Pregnancy** Risk Summary Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm or loss of pregnancy when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in Full Prescribing Information]*. There are no available data on the use of PEMAZYRE in pregnant women. Oral administration of pemigatinib to pregnant rats during the period of organogenesis at maternal plasma exposures below the human exposure at the clinical dose of 13.5 mg resulted in fetal malformations, fetal growth retardation, and embryo-fetal death (*see Data*). Advise pregnant women of the potential risk to a fetus. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Data *Animal Data* Once daily oral administration of pemigatinib to pregnant rats during the period of organogenesis resulted in 100% embryofetal mortality due to post-implantation loss at doses ≥ 0.3 mg/kg (approximately 0.6 times the human exposure based on AUC at the clinical dose of 13.5 mg). Fetal survival was unaffected at 0.1 mg/kg per day; however, once daily oral administration of pemigatinib at the 0.1 mg/kg dose level (approximately 0.2 times the human exposure based on AUC at the clinical dose of 13.5 mg) resulted in reduced mean fetal body weight and an increase in fetal skeletal and visceral malformations, major blood vessel variations, and reduced ossification. **Lactation** Risk Summary There are no data on the presence of pemigatinib or its metabolites in human milk or their effects on either the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children from PEMAZYRE, advise women not to breastfeed during treatment and for 1 week after the final dose. **Females and Males of Reproductive Potential** Pregnancy Testing Verify pregnancy status of females of reproductive potential prior to initiating PEMAZYRE *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. Contraception PEMAZYRE can cause fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. **Females** Advise females of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Males** Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Pediatric Use** The safety and effectiveness of PEMAZYRE have not been established in pediatric patients. Animal Toxicity Data In 4- or 13-week repeat-dose toxicology studies in rats and non-human primates, animals displayed toxicities in bone and teeth at pemigatinib exposures lower than the human exposure at the clinical dose of 13.5 mg. Physeal and cartilage dysplasia were present in multiple bones in both species, and tooth (incisor) abnormalities (complete loss of ameloblasts with associated secondary changes) occurred in rats. Six weeks after cessation of dosing, these findings did not show complete evidence of recovery, and additional tooth-related findings (mal-aligned, whitened, broken, and trimmed/thinned incisors) developed in the 13-week study. **Geriatric Use** In FIGHT-202, 32% of patients were 65 years and older, and 8% of patients were 75 years and older. No overall differences in safety or effectiveness were observed between these patients and younger patients. **Renal Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m^2, estimated by Modification of Diet in Renal Disease [MDRD] equation) *[see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild or moderate renal impairment (eGFR 30 to 89 mL/min/1.73 m^2). No dosage adjustment is recommended for patients with end-stage renal disease (eGFR < 15 mL/min/1.73 m^2) who are receiving intermittent hemodialysis. *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **Hepatic Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe hepatic impairment (total bilirubin > 3 × ULN with any AST) *[see Dosage and Administration (2.6) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild (total bilirubin > upper limit of normal [ULN] to 1.5 × ULN or AST > ULN) or moderate (total bilirubin >1.5–3 × ULN with any AST) hepatic impairment *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*.

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US Trichomonas Insights:

The Importance of Testing for Trichomonas

Estimated global incidence of Trichomonas vaginalis compared to three other curable STIs (Chlamydia trachomatis, Neisseria gonorrhoeae, and syphilis) according to WHO

BY SEKISUI DIAGNOSTICS

Trichomoniasis is a common, curable, non-viral sexually transmitted infection caused by a motile protozoan parasite called Trichomonas vaginalis. Trichomonas (sometimes referred to as "Trich") infects the vagina and sometimes urethra and is transmitted during unprotected sex. It is roughly as big as a white blood cell, and it is thought to be responsible for approximately 15-20% of symptomatic vaginitis infections.

Both men and women can get a Trichomonas infection, but it is more commonly detected in women.

Formerly considered a nuisance infection, trichomoniasis is now recognized as a cause of serious health problems. Nevertheless, it continues to be highly underdiagnosed and under-treated.

	Normal	Trichomoniasis	Bacterial Vaginosis	Candida
Odor	Slightly salty to unnoticeable	Sometimes foul or fishy	Unpleasant, foul, fishy, or musty	None
Discharge	Clear to slightly milky	Yellow-green-grey, frothy, or sticky	Thin, milk white or grey, usually increased	Thick, curdy, and white, like cottage cheese
Discomfort	None	Sometimes itching, painful urination	Itching/burning sometimes present	Vaginal itching or burning is usually present
Cause	Balance	Parasite	Bacteria	Candida *albicans*
Sexually transmitted		Yes	Controvertial	No

Incidence

The World Health Organization estimates an incidence of 276 million new cases of T vaginalis each year and a prevalence of 187 million infected individuals between the age of 15 and 49 years old. In the United States, the Centers for Disease Control and Prevention estimates that there were more than two million trichomoniasis infections in 2018. The incidence of trichomoniasis in Europe is similar to that in the United States. In Africa, the prevalence of trichomoniasis may be much higher. The prevalence of vaginal T vaginalis infection was estimated to be 11-25% among African study populations.

Symptoms

Only about 30% develop any symptoms of trichomoniasis. When symptoms do occur, they range from mild irritation to severe inflammation. Some people with symptoms get them within 5 to 28 days after being infected. Others do not develop symptoms until much later, and those symptoms can come and go. It is important to note that people without symptoms can still pass the infection on to others. Trichomonas symptoms in women can be differentiated from other common forms of vaginitis.

Men with trichomoniasis may notice:

- Itching or irritation inside the penis
- Burning after urination or ejaculation
- Discharge from the penis

Complications

Trichomoniasis can be treated with medication but left untreated it can last for months or even years and lead to serious complications. For example, trichomoniasis can cause genital inflammation, which makes it easier to get infected with HIV or to pass the HIV virus on to a sex partner. Pregnant women with trichomoniasis are more likely to have their babies too early (preterm delivery). Also, babies born to infected mothers are more likely to have a low birth weight (less than 5.5 pounds).

A woman with untreated trichomoniasis has a greater chance of having an infected uterus and Fallopian tubes. This infection, called pelvic inflammatory disease, can cause belly pain, fever, and perhaps the inability to have children (infertility), a pregnancy outside the uterus (ectopic pregnancy), and chronic pelvic pain.

Treatment and Prevention

Since it is a STI, the best way to prevent Trichomonas is to have protected sex. Re-infections with Trichomoniasis are also possible. The best way to avoid re-infections is for the patient to avoid having sex for seven days after treatment has been administered. Trichomoniasis is typically treated with the following antibiotics: Tinidazole 500mg x 4 tablets as a single dose or Metronidazole twice a day for 5-7 days.

"A major barrier to sexually transmitted infections (STIs) control and prevention is the unavailability of reliable, low-cost, point-of-care tests (POCTs) which allow diagnosis and treatment in a single visit."

—WHO

Diagnosing trichomoniasis

STD testing, including a trichomoniasis test, may be recommended for people with certain risk factors, including sex without a condom, multiple sex partners, or a history of other sexually transmitted diseases. Because the majority of men are asymptomatic carriers, the diagnosis of T vaginalis is usually not made, and the male partner is identified and treated with metronidazole at the same time that the female partner is treated.

A number of testing options are available. Choices are made based on accuracy, timeliness and cost:

Method	Sensitivity	Specificity	Time to result	Equipment required	Specialized training required?	Typical setting to perform test	Comments
 Wet Mount	44-68%	100%	Minutes	Microscope	No	Physician Office Lab, Hospital	Labor cost, low sensitivity, requires live organism
 Culture	44-75%	100%	1-5 days	Incubator, culture media	No	Hospital, reference lab	Low-cost, long turn-around time
 Molecular	95.3-100%	99.6%	30 minutes - Hours	Thermal Cycler	No	Hospital, reference lab	Higher cost
 OSOM Trichomonas	82-95%	100%	10 minutes	None	Yes	Physician Office Lab, Hospital	Test and treat in one visit

Microscopy
- The most commonly used diagnostic test is wet preparation microscopy.
- A swab is used to collect material from the vaginal fornix and placed into a small amount, 0.5 to 1.0 ml, of normal saline.
- A drop of the saline preparation is placed on a slide and viewed with a microscope with a 40× objective.

Culture
- Refers to the deliberate growing of cells, especially microorganisms, in a solid or liquid medium (e.g. agar, gelatin), as of bacteria in a Petri dish.
- Incubation periods ranging from two to seven days are required to identify T vaginalis in culture.

Molecular
- Nucleic amplification assay tests (NAATs) are based on rRNA extraction from specimens, followed by transcription-mediated amplification of captured rRNA.
- The use of this target provides a natural boost to the limit of detection since 102 to 103 copies exist within each organism.

Lateral Flow
- Immunochromatographic enzyme assay performed on a capillary flow dipstick device with a vaginal swab specimen, such as the OSOM Trichomonas Test.
- The assay relies on a latex-tagged antibody to bind specifically to trichomonas proteins and a secondary capture antibody to bind the complex to the lateral-flow device.

OSOM® Trichomonas test

The OSOM Trichomonas rapid test has improved sensitivity, specificity, specimen stability, and compares favorably to NAATs [nucleic amplification assay tests], with reported sensitivities of 83%–90%. Suitable for Laboratory and Point-of-Care (POC) setting:
- Offers 95% agreement with culture and wet mount combined
- A test-and-treat approach in one visit
- Detects the antigen; does not require live organism
- Yields results in 10 minutes or less
- Offers objective, easy-to-read two-color results
- Is the only CLIA-waived rapid test for the detection of trichomoniasis

> "Use of this assay as a point-of-care test for the detection of trichomoniasis in an emergency department has been shown to prevent overtreatment of vaginal infections compared with historical controls before the introduction of the POC test, resulting in good antibiotic stewardship."
>
> —Gaydos et al. 2017

Advantages of a Test and Treat Approach
- Prevent spread – Quick diagnosis allows the clinician to provide appropriate and immediate treatment to prevent further spread of Trichomoniasis
- Patient compliance – Ensures the patient starts medication immediately
- Prevent inappropriate treatment – Accurate diagnosis results in avoidance of syndromic management



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SEKISUI DIAGNOSTICS
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NEVIS:

A SECRET WORTH SHARING

BY BRANDI NIMMO



IT'S LIKE A SECRET THAT NOBODY KNOWS.

You mention in passing that you've just been to paradise, and it's an island called Nevis in the West Indies. Chances are they've never heard of it. But when you come across someone who has been, their eyes light up, and there's an instant exchange of enlightenment as if to say, "I've been there, I know what you're feeling."

All over the world, there are beautiful places, but this corner of it is different. It's special. It is a feeling you have to experience. It's a special little secret that needs to be shared with others, not just whispered but shouted from its volcanic peak.

MDescapes







That mountain, Nevis Peak, rests 3200 feet high upon the small island's 36-mile circumference. Thought to be one of the most unspoiled treasures in the Caribbean, this island was once a land of coconut and sugar plantations providing more than 20% of the British Empire's sugar yield. Recent fame as the birthplace of U.S. founding father Alexander Hamilton, "dropped in the middle of a forgotten spot in the Caribbean in Providence," lyrics of the famous Broadway musical.

This "forgotten spot" is located in the Leeward island chain of the West Indies and part of a two-island country, separated from its more bustling sister island to the northwest, St. Kitts, by a two-mile channel called The Narrows. "Two islands, one federation, but two worlds," according to Alexis Arthorton, Nevis Tourism Authority spokesperson. "Nevis provides real island living," Arthorton touts, "We rush slowly here...No stoplights, no fast food, no movie theaters." No buildings taller than palm trees, a place where the number of goats and donkeys rival the number of residents, you feel like you've stepped back in time. The demographic is a more mature group who want to live, relax, and be with nature. But for those that want the nightlife, casinos, and St. Kitts' action, it's just a 20-minute boat ride to St. Christoff harbor. Two islands, one federation but two very different worlds.

Just over 30 years ago, Four Seasons came to this verdant landscape with a vision for the majestic 350 acres set at the base of Nevis Peak down to the emerald Caribbean coastline. A dream was imagined and executed, a gorgeous award-winning luxury resort. The island economy once relied heavily on agriculture and fishing, sending young graduates off the island to find work. Four Seasons brought new economic life and growth for the Nevisian island and people. The Four Seasons Resort has a dedicated staff proudly comprised of 95 percent Nevisian team members. MacKee France, Director of Guest Experiences, has been a member of the Four Seasons family from day one. He feels the key to the success of this Resort is the people. There is a level of quality in service that guests expect with the brand, and Nevis is no exception to that rule. Some would say that the presumptions of excellence are exceeded because of the quality of people on the island. "The happiness is already installed," says France, "Our team members come to us 90% ready, with their hearts open to serve. We just need to train them on the final 10%." Many of the Resort's return guests are always pleasantly surprised and happy to reunite with the sweet Navisian smiles that have welcomed them over the years, team members still there to share in making new magical memories.

The commitment that Four Seasons made to the island years ago continued by the decision to embark on a multi-million dollar enhancement project in 2018. The multi-phase renovations, over several years, are now complete and ready to be enjoyed. A highlight of the revitalized Resort; all 189 guest rooms and suites have been reimagined with a light, clean and fresh décor, with textile touches of island life throughout, like the iconic Nevis ambassador, the green vervet monkey.

The design team responsible for the new concept, TAL Design Studios, wanted to maintain the quaint and intimate reputation





of the island as an untouched tropical destination. TAL Founder Todd-Avery Lenahan said, "...design is not meant to be a complete overhaul but rather the realization of a new vision for the resort that speaks to the modern Four Seasons traveler." Lenahan assures they succeeded while still preserving the humble charm of the Resort's small island home.

Dotting the hillside along the golf course, Four Seasons Resort has over 50 villas to accommodate any special gathering for larger groups or families. Whether a guest room or suite, villa or estate home, with a mountain view, ocean view, or both, your stay will be extraordinary.

The new eateries have chic, fashionable styles and reflect the Caribbean's soul and spirit. The enhancements extend across all of the Resort's dining options; guests can enjoy relaxed beachside Caribbean-American fare at On the Dune, soak in coastal Mediterranean cuisine at EsQuilina, or modern Caribbean classics at Mango. Fill up on the flavors at Kastawey, traditional Caribbean BBQ, and stop in for a nightcap at a rum-fuelled Crowned Monkey Bar, which features the bespoke Crowned Monkey Rum, only available at Four Seasons Resort Nevis. The cuisine at all options exceeds the high standard for which the Four Seasons is renowned. One would expect nothing less.

Once you have heard about this special secret, you have to discover for yourself if it is true. You fly to St. Kitts Robert Bradshaw Airport (Four Seasons greeters whisk away your luggage, which you don't see again until you're in your suite), a quick

The island is still special more than three decades later; this paradise has stayed true to the promise of perfection, welcoming global visitors to this island home the moment their feet touch the dock.

shuttle drive to the harbor, and a fun 20-minute boat ride while you enjoy a bottle of Ting or Rum punch. Staff members await your arrival as the water taxi pulls up to the newly renovated and expanded "T" shaped pier. A favorite spot for the sundowners club with low lighting on the perimeter of the 7000 square foot surface and conversational clusters of comfy chairs to watch the many memorable sunsets. It's here that you feel the tropical breeze in your hair, exhale out all the stress and inhale all the beauty. You're home.

Years ago, when Four Seasons Founder and Chairman Isadore Sharp first stepped foot on the palm tree-lined Pinney's Beach, it was only a few short years before a new legacy within Four Sea-



sons Hotels and Resorts emerged. At the time, Sharp said of the unique spot, "Nevis was really an unknown; it wasn't on anyone's radar screen." The island is still special more than three decades later; this paradise has stayed true to the promise of perfection, welcoming global visitors to this island home the moment their feet touch the dock.

Beyond the dock, there are infinite perfect places in this one perfect paradise to see, play, eat and do: an 18 hole Robert Trent Jones golf course where every hole has a gorgeous view, tennis courts featuring red clay, hard court, astroturf, and top-rated tennis instruction, basketball court, garden games with bocce ball court and over-sized chess and shuffleboards. If you want to unwind by the water, there are three distinct choices of pools; The new signature Limin' Pool is the centerpiece for the Resort, offering incredible views from the Great House lobby straight out to the Caribbean Sea horizon. The Calypso Pool is next to the ocean, great for families, and features an 83-foot swimming lane and a splash pad for children. The Soca Pool is more private and designed for adults with relaxation as the priority. All have infinity water features, surrounded by new landscaping, comfortable lounging chairs, and attentive pool staff to bring chilled scented towels, water face mistings, and cold drinks as you soak up the sun.

Three miles of golden sand stretches along Pinney's Beach, where bright yellow umbrellas contrast against the blue Caribbean Sea to the west. This moment is what you've been dreaming about, laying upon a lounger sipping on a yummy drink as Raheem offers you a mango popsicle. Or perhaps you've opted for one of the adorable beach cabanas for the entire day with a hammock, t.v., wifi, attendants like sweet Nabrisca are there for your every whim. Either option is close to all of the on-property water activities to enjoy. Paddle-boarding, Hobie cat, water-skiing, snorkeling tours, you name it, they have it. Their staff is eager to assist you with any equipment needed to enjoy the beautiful blue.

You can stay on top of your fitness goals with the workout equipment, exercise classes, and private training available at the sports pavilion. If pampering is your passion, The Spa is a tropical oasis for massage therapy and salon services. Gorgeous landscaped gardens, volcanic-stone whirlpool, Japanese-inspired cold plunge pool surround colorful little gingerbread-trimmed treatment cottages where mind and body can recharge. Indulge with a signature Nevisian massage; this full-body experience incorporates a locally infused blend of scents, spices, and oils of the Caribbean. Ruthlynn works her magic on your muscles, and the tension evaporates.

Throw in a few memorable experiences to round off the adventure. Hot sauce-making class with Four Seasons chef and infamous island figure Llewellyn Clark. A fun culinary lesson and a bottle of your efforts to take home to remember it by. Or maybe a colorful tour of Nevis, exploring the quaint shops of the capital Charlestown, joining local Nevisians on the banks of the 107 degrees Bath Stream, and enjoying health benefits that have thrived in local lore for over two centuries. Hiking Nevis Peak and discovering waterfalls and fauna rejuvenates the soul. It is



When something is this good, it's tempting to keep it on the down-low, selfishly save it for yourself.

gaining education on the abundant fruit grown on the island and all of the medicinal benefits of nature's candy on the Orchard Garden Tour. Experience yummy farm-to-table fare at the very colorful and quaint Paradise, a local haunt situated in the foothills. Every offering by owner Karen Belle pops of freshness, accentuated by the flavor of island spices. Round off the day with a late afternoon golf cart ride, the green monkey tour, spy on their mischievous activities—so many things to experience both on and off Resort that awaken the senses and soothe the soul.

Four Seasons Resort Nevis has delivered authentic Caribbean luxury with genuine Nevisian hospitality for the past three decades.

It has seen many firsts, including earning the first AAA Five-Diamond Award within the brand. Nevis Resort and Spa remain a crown jewel upon Four Seasons tiara, receiving recognition from Condé Nast Traveler and Forbes, among others. Along with the Resort receiving significant awards, many of its team members have also shared in the spotlight, perhaps no more than self-taught Mixologist Kendie Williams. She has made a name for herself within the bartending world for her creative cocktail creations, named "Caribbean Bartender of the Year" numerous times.

In the writings of native son Alexander Hamilton (1727): "I leave them to my Reader, with the old Proverb to accompany them, that the Proof of the Pudding is in eating it." The proof of this paradise is in the people. The secret sauce is the Nevisians and their limin' way of life. Their island contentment with their smiling faces is contagious. When something is this good, it's tempting to keep it on the down-low, selfishly save it for yourself.

Or you can choose to spread the love.

According to island ikon, MacKee France, there is a superstition attached to the national tree of Nevis, the Royal Poinciana or Flamboyant tree. The islanders call it the Shak Shak tree, and some seeds can be found after you crack open the seedpods that grow following the flowering season. If someone is genuine and gives you seeds from a Shak Shak tree, the belief is that you will have "good luck, goodwill, prosperity, progress, and harmony." France continues with a condition of the promise, "You must not lose the seeds; you put them in a special place and keep them safe. You can share one of your seeds with someone you care about so that they, too, will have good luck. You should spread the love."

Like the superstitious seeds, shared with genuineness, the news of Nevis needs to be shared. This special place, this secret that nobody knows, isn't meant to be kept quiet but shouted from Nevis peak for all to hear. Spread the love of this island with others.

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See how you can help your patients gain control of their psoriatic symptoms with **CIMZIA**, a different kind of anti-TNF[2-4]

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IMPORTANT SAFETY INFORMATION
Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

CIMZIA has demonstrated safety and efficacy in a pivotal study for adult patients with active psoriatic arthritis[1]

In psoriatic arthritis patients, the primary efficacy end point at Week 12 in RAPID-PsA was ACR20, with 55% of CIMZIA patients achieving ACR20 at Week 12 vs 24% of placebo patients. Similar results were seen in the 20% of patients with prior biologic experience.

RAPID-PsA was a randomized, multicenter, phase 3 trial in patients with PsA. The trial was double-blind and placebo-controlled through week 24 and dose-blind to week 48.

Results may vary; every person taking CIMZIA is different and responds differently to therapy. See more at **CIMZIAhcp.com**.

Please see the adjacent page for **Important Safety Information** and the following pages for a brief summary of full **Prescribing Information**, or visit **CIMZIAhcp.com**.

Indications

- CIMZIA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- CIMZIA is indicated for the treatment of adults with active psoriatic arthritis.

Important Safety Information

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDs.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

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

Please see the following pages for brief summary of full **Prescribing Information**, or visit **CIMZIAhcp.com**.

ACR20, American College of Rheumatology criteria for 20% response; PsA, psoriatic arthritis.

REFERENCES: 1. CIMZIA® [prescribing information]. Smyrna, GA: UCB, Inc. **2.** van der Heijde D, Deodhar A, FitzGerald O, et al. 4-year results from the RAPID-PsA phase 3 randomised placebo-controlled trial of certolizumab pegol in psoriatic arthritis. *RMD Open.* 2018;4(1):e000582. **3.** Data on file. UCB, Inc.; Smyrna, GA. **4.** Gladman D, Fleischmann R, Coteur G, Woltering F, Mease PJ. Effect of certolizumab pegol on multiple facets of psoriatic arthritis as reported by patients: 24-week patient-reported outcome results of a phase III, multicenter study. *Arthritis Care Res (Hoboken).* 2014;66(7):1085-1092.

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PROFESSIONAL BRIEF SUMMARY—CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

CIMZIA® (certolizumab pegol)

WARNINGS:

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death *[see Warnings and Precautions and Adverse Reactions]*. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

CIMZIA should be discontinued if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before CIMZIA use and during therapy. Treatment for latent infection should be initiated prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens including Legionella and Listeria.**

The risks and benefits of treatment with CIMZIA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy. *[see Warnings and Precautions and Adverse Reactions]*.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member *[see Warnings and Precautions]*. CIMZIA is not indicated for use in pediatric patients.

INDICATIONS AND USAGE

CIMZIA is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. CIMZIA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). CIMZIA is indicated for the treatment of adult patients with active psoriatic arthritis (PsA). CIMZIA is indicated for the treatment of adults with active ankylosing spondylitis (AS). CIMZIA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. CIMZIA is indicated for adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS

Risk of Serious Infections *(see also Boxed Warning)*

Patients treated with CIMZIA are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death.

Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic pathogens including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis and tuberculosis have been reported with TNF blockers. Patients have frequently presented with disseminated rather than localized disease.

Treatment with CIMZIA should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g. corticosteroids or methotrexate) may be at a greater risk of infection. The risks and benefits of treatment should be considered prior to initiating therapy in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis
- with a history of an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis
- with underlying conditions that may predispose them to infection

Tuberculosis

Cases of reactivation of tuberculosis or new tuberculosis infections have been observed in patients receiving CIMZIA, including patients who have previously or concomitantly received treatment for latent or active tuberculosis. Reports included cases of pulmonary and extrapulmonary (i.e., disseminated) tuberculosis. Evaluate patients for tuberculosis risk factors and test for latent infection prior to initiating CIMZIA and periodically during therapy.

Treatment of latent tuberculosis infection prior to therapy with TNF-blocking agents has been shown to reduce the risk of tuberculosis reactivation during therapy. Prior to initiating CIMZIA, assess if treatment for latent tuberculosis is needed; and consider an induration of 5 mm or greater a positive tuberculin skin test result, even for patients previously vaccinated with Bacille Calmette-Guerin (BCG).

Consider anti-tuberculosis therapy prior to initiation of CIMZIA in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Despite previous or concomitant treatment for latent tuberculosis, cases of active tuberculosis have occurred in patients treated with CIMZIA. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with CIMZIA. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision of whether initiating anti-tuberculosis therapy is appropriate for an individual patient.

Strongly consider tuberculosis in patients who develop a new infection during CIMZIA treatment, especially in patients who have previously or recently traveled to countries with a high prevalence of tuberculosis, or who have had close contact with a person with active tuberculosis.

Monitoring

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy. Tests for latent tuberculosis infection may also be falsely negative while on therapy with CIMZIA.

CIMZIA should be discontinued if a patient develops a serious infection or sepsis. A patient who develops a new infection during treatment with CIMZIA should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for an immunocompromised patient, and appropriate antimicrobial therapy should be initiated.

Invasive Fungal Infections

For patients who reside or travel in regions where mycoses are endemic, invasive fungal infection should be suspected if they develop a serious systemic illness. Appropriate empiric antifungal therapy should be considered while a diagnostic workup is being performed. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection.

When feasible, the decision to administer empiric antifungal therapy in these patients should be made in consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections and should take into account both the risk for severe fungal infection and risks of antifungal therapy.

Malignancies

In the controlled portions of clinical studies of some TNF blockers, more cases of malignancies have been observed among patients receiving TNF blockers compared to control patients. During controlled and open-labeled portions of CIMZIA studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate (95% confidence interval) of 0.5 (0.4, 0.7) per 100 patient-years among 4,650 CIMZIA-treated patients versus a rate of 0.6 (0.1, 1.7) per 100 patient-years among 1,319 placebo-treated patients. During CIMZIA studies of psoriasis, malignancies (excluding non-melanoma skin cancer) were observed corresponding to an incidence rate of 0.5 (0.2, 1.0) per 100 subject-years among a total of 995 subjects who received CIMZIA. The size of the control group and limited duration of the controlled portions of the studies precludes the ability to draw firm conclusions.

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which CIMZIA is a member. Approximately half the cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of different malignancies and included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months of therapy (range 1 to 84 months). Most of the patients were receiving concomitant immunosuppressants. These cases were reported post-marketing and are derived from a variety of sources including registries and spontaneous post-marketing reports. CIMZIA is not indicated for use in pediatric patients.

In the controlled portions of clinical trials of all the TNF blockers, more cases of lymphoma have been observed among patients receiving TNF blockers compared to control patients. In controlled studies of CIMZIA for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 CIMZIA-treated patients and one case of Hodgkin's lymphoma among 1,319 placebo-treated patients.

In the CIMZIA RA clinical trials (placebo-controlled and open label) a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. In the CIMZIA PsO clinical trials (placebo-controlled and open label) there was one case of Hodgkin's lymphoma.

Rates in clinical studies for CIMZIA cannot be compared to the rates of clinical trials of other TNF blockers and may not predict the rates observed when CIMZIA is used in a broader patient population. Patients with Crohn's disease that require chronic exposure to immunosuppressant therapies may be at higher risk than the general population for the development of lymphoma, even in the absence of TNF blocker therapy *[see Adverse Reactions]*. The potential role of TNF blocker therapy in the development of malignancies in adults is not known.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA. The majority of reported TNF blocker cases occurred in adolescent and young adult males with Crohn's disease or ulcerative colitis. Almost all of these patients had received treatment with the immunosuppressants azathioprine and/or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants. The potential risk of using a TNF blocker in combination with azathioprine or 6-MP should be carefully considered.

Cases of acute and chronic leukemia have been reported in association with post-marketing TNF-blocker use in RA and other indications. Even in the absence of TNF-blocker therapy, patients with RA may be at a higher risk (approximately 2-fold) than the general population for the development of leukemia.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF blockers, including CIMZIA. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

Heart Failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including CIMZIA. CIMZIA has not been formally studied in patients with CHF; however, in clinical studies in patients with CHF with another TNF blocker, worsening congestive heart failure (CHF) and increased mortality due to CHF

were observed. Exercise caution in patients with heart failure and monitor them carefully *[see Adverse Reactions]*.

Hypersensitivity Reactions

The following symptoms that could be compatible with hypersensitivity reactions have been reported rarely following CIMZIA administration to patients: angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria. Some of these reactions occurred after the first administration of CIMZIA. If such reactions occur, discontinue further administration of CIMZIA and institute appropriate therapy. There are no data on the risks of using CIMZIA in patients who have experienced a severe hypersensitivity reaction towards another TNF blocker; in these patients caution is needed *[see Adverse Reactions]*. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Hepatitis B Virus Reactivation

Use of TNF blockers, including CIMZIA, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. In some instances, HBV reactivation occurring in conjunction with TNF blocker therapy has been fatal. The majority of reports have occurred in patients concomitantly receiving other medications that suppress the immune system, which may also contribute to HBV reactivation.Test patients for HBV infection before initiating treatment with CIMZIA. For patients who test positive for HBV infection, consultation with a physician with expertise in the treatment of hepatitis B is recommended. Adequate data are not available on the safety or efficacy of treating patients who are carriers of HBV with anti-viral therapy in conjunction with TNF blocker therapy to prevent HBV reactivation. Patients who are carriers of HBV and require treatment with CIMZIA should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy.

In patients who develop HBV reactivation, discontinue CIMZIA and initiate effective anti-viral therapy with appropriate supportive treatment. The safety of resuming TNF blocker therapy after HBV reactivation is controlled is not known. Therefore, exercise caution when considering resumption of CIMZIA therapy in this situation and monitor patients closely.

Neurologic Reactions

Use of TNF blockers, of which CIMZIA is a member, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease, including multiple sclerosis, and with peripheral demyelinating disease, including Guillain-Barré syndrome. Exercise caution in considering the use of CIMZIA in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with CIMZIA *[see Adverse Reactions]*.

Hematological Reactions

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Adverse reactions of the hematologic system, including medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) have been infrequently reported with CIMZIA *[see Adverse Reactions]*. The causal relationship of these events to CIMZIA remains unclear.

Although no high risk group has been identified, exercise caution in patients being treated with CIMZIA who have ongoing, or a history of, significant hematologic abnormalities. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on CIMZIA. Consider discontinuation of CIMZIA therapy in patients with confirmed significant hematologic abnormalities.

Use with Biological Disease-Modifying Antirheumatic Drugs (Biological DMARDs)

Serious infections were seen in clinical studies with concurrent use of anakinra (an interleukin-1 antagonist) and another TNF blocker, etanercept, with no added benefit compared to etanercept alone. A higher risk of serious infections was also observed in combination use of TNF blockers with abatacept and rituximab. Because of the nature of the adverse events seen with this combination therapy, similar toxicities may also result from the use of CIMZIA in this combination. Therefore, the use of CIMZIA in combination with other biological DMARDs is not recommended *[see Drug Interactions]*.

Autoimmunity

Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with CIMZIA, discontinue treatment *[see Adverse Reactions]*.

Immunizations

Patients treated with CIMZIA may receive vaccinations, except for live or live attenuated vaccines. No data are available on the response to live vaccinations or the secondary transmission of infection by live vaccines in patients receiving CIMZIA.

In a placebo-controlled clinical trial of patients with rheumatoid arthritis, no difference was detected in antibody response to vaccine between CIMZIA and placebo treatment groups when the pneumococcal polysaccharide vaccine and influenza vaccine were administered concurrently with CIMZIA. Similar proportions of patients developed protective levels of anti-vaccine antibodies between CIMZIA and placebo treatment groups; however, patients receiving CIMZIA and concomitant methotrexate had a lower humoral response compared with patients receiving CIMZIA alone. The clinical significance of this is unknown.

Immunosuppression

Since TNF mediates inflammation and modulates cellular immune responses, the possibility exists for TNF blockers, including CIMZIA, to affect host defenses against infections and malignancies. The impact of treatment with CIMZIA on the development and course of malignancies, as well as active and/or chronic infections, is not fully understood *[see Warnings and Precautions and Adverse Reactions]*. The safety and efficacy of CIMZIA in patients with immunosuppression has not been formally evaluated.

ADVERSE REACTIONS

The most serious adverse reactions were:

- Serious Infections *[see Warnings and Precautions]*
- Malignancies *[see Warnings and Precautions]*
- Heart Failure *[see Warnings and Precautions)]*

Clinical Trials Experience

Because clinical studies are conducted under widely varying and controlled conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug, and may not predict the rates observed in a broader patient population in clinical practice.

In premarketing controlled trials of all patient populations combined the most common adverse reactions (≥ 8%) were upper respiratory infections (18%), rash (9%) and urinary tract infections (8%).

Adverse Reactions Most Commonly Leading to Discontinuation of Treatment in Premarketing Controlled Trials

The proportion of patients with Crohn's disease who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for CIMZIA and 7% for placebo. The most common adverse reactions leading to the discontinuation of CIMZIA (for at least 2 patients and with a higher incidence than placebo) were abdominal pain (0.4% CIMZIA, 0.2% placebo), diarrhea (0.4% CIMZIA, 0% placebo), and intestinal obstruction (0.4% CIMZIA, 0% placebo).

The proportion of patients with rheumatoid arthritis who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for CIMZIA and 2.5% for placebo. The most common adverse reactions leading to discontinuation of CIMZIA were tuberculosis infections (0.5%); and pyrexia, urticaria, pneumonia, and rash (0.3%).

Controlled Studies with Crohn's Disease

The data described below reflect exposure to CIMZIA at 400 mg subcutaneous dosing in studies of patients with Crohn's disease. In the safety population in controlled studies, a total of 620 patients with Crohn's disease received CIMZIA at a dose of 400 mg, and 614 subjects received placebo (including subjects randomized to placebo in Study CD2 following open label dosing of CIMZIA at Weeks 0, 2, 4). In controlled and uncontrolled studies, 1,564 patients received CIMZIA at some dose level, of whom 1,350 patients received 400 mg CIMZIA. Approximately 55% of subjects were female, 45% were male, and 94% were Caucasian. The majority of patients in the active group were between the ages of 18 and 64.

During controlled clinical studies, the proportion of patients with serious adverse reactions was 10% for CIMZIA and 9% for placebo. The most common adverse reactions (occurring in ≥ 5% of CIMZIA-treated patients, and with a higher incidence compared to placebo) in controlled clinical studies with CIMZIA were upper respiratory infections (e.g. nasopharyngitis, laryngitis, viral infection) in 20% of CIMZIA-treated patients and 13% of placebo-treated patients, urinary tract infections (e.g. bladder infection, bacteriuria, cystitis) in 7% of CIMZIA-treated patients and in 6% of placebo-treated patients, and arthralgia (6% CIMZIA, 4% placebo).

Other Adverse Reactions

The most commonly occurring adverse reactions in controlled trials of Crohn's disease were described above. Other serious or significant adverse reactions reported in controlled and uncontrolled studies in Crohn's disease and other diseases, occurring in patients receiving CIMZIA at doses of 400 mg or other doses include:

Blood and lymphatic system disorders: Anemia, leukopenia, lymphadenopathy, pancytopenia, and thrombophilia.

Cardiac disorders: Angina pectoris, arrhythmias, atrial fibrillation, cardiac failure, hypertensive heart disease, myocardial infarction, myocardial ischemia, pericardial effusion, pericarditis, stroke and transient ischemic attack.

Eye disorders: Optic neuritis, retinal hemorrhage, and uveitis.

General disorders and administration site conditions: Bleeding and injection site reactions.

Hepatobiliary disorders: Elevated liver enzymes and hepatitis.

Immune system disorders: Alopecia totalis.

Psychiatric disorders: Anxiety, bipolar disorder, and suicide attempt.

Renal and urinary disorders: Nephrotic syndrome and renal failure.

Reproductive system and breast disorders: Menstrual disorder.

Skin and subcutaneous tissue disorders: Dermatitis, erythema nodosum, and urticaria.

Vascular disorders: Thrombophlebitis, vasculitis.

Controlled Studies with Rheumatoid Arthritis

CIMZIA was studied primarily in placebo-controlled trials and in long-term follow-up studies. The data described below reflect the exposure to CIMZIA in 2,367 RA patients, including 2,030 exposed for at least 6 months, 1,663 exposed for at least one year and 282 for at least 2 years; and 1,774 in adequate and well-controlled studies. In placebo-controlled studies, the population had a median age of 53 years at entry; approximately 80% were females, 93% were Caucasian and all patients were suffering from active rheumatoid arthritis, with a median disease duration of 6.2 years. Most patients received the recommended dose of CIMZIA or higher.

Table 1 summarizes the reactions reported at a rate of at least 3% in patients treated with CIMZIA 200 mg every other week compared to placebo (saline formulation), given concomitantly with methotrexate.

Table 1: Adverse Reactions Reported by ≥3% of Patients Treated with CIMZIA Dosed Every Other Week during Placebo-Controlled Period of Rheumatoid Arthritis Studies, with Concomitant Methotrexate.

Adverse Reaction (Preferred Term)	Placebo+ MTX# (%) N =324	CIMZIA 200 mg EOW + MTX (%) N =640
Upper respiratory tract infection	2	6
Headache	4	5
Hypertension	2	5
Nasopharyngitis	1	5
Back pain	1	4
Pyrexia	2	3
Pharyngitis	1	3
Rash	1	3
Acute bronchitis	1	3
Fatigue	2	3

#EOW = Every other Week, MTX = Methotrexate.

Hypertensive adverse reactions were observed more frequently in patients receiving CIMZIA than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs.

Patients receiving CIMZIA 400 mg as monotherapy every 4 weeks in rheumatoid arthritis controlled clinical trials had similar adverse reactions to those patients receiving CIMZIA 200 mg every other week.

Other Adverse Reactions

Other infrequent adverse reactions (occurring in less than 3% of RA patients) were similar to those seen in Crohn's disease patients.

Psoriatic Arthritis Clinical Study

CIMZIA has been studied in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled trial. The safety profile for patients with PsA

treated with CIMZIA was similar to the safety profile seen in patients with RA and previous experience with CIMZIA.

Ankylosing Spondylitis Clinical Study
CIMZIA has been studied in 325 patients with axial spondyloarthritis of whom the majority had ankylosing spondylitis (AS) in a placebo-controlled study (AS-1). The safety profile treated with CIMZIA was similar to the safety profile seen in patients with RA.

Non-radiographic Axial Spondyloarthritis Clinical Study
CIMZIA has been studied in 317 patients with non-radiographic axial spondyloarthritis (nr-axSpA-1). The safety profile for patients with nr-axSpA treated with CIMZIA was similar to the safety profile seen in patients with RA and previous experience with CIMZIA.

Plaque Psoriasis Clinical Studies
In clinical studies, a total of 1112 subjects with plaque psoriasis were treated with CIMZIA. Of these, 779 subjects were exposed for at least 12 months, 551 for 18 months, and 66 for 24 months.

Data from three placebo-controlled studies (Studies PS-1, PS-2, and PS-3) in 1020 subjects (mean age 46 years, 66% males, 94% white) were pooled to evaluate the safety of CIMZIA *[see Clinical Studies (14)]*.

Placebo-Controlled Period (Week 0-16)
In the placebo-controlled period of Studies PS-1, PS-2 and PS-3 in the 400 mg group, adverse events occurred in 63.5% of subjects in the CIMZIA group compared to 61.8% of subjects in the placebo group. The rates of serious adverse events were 4.7% in the CIMZIA group and 4.5% in the placebo group. Table 2 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the CIMZIA group than in the placebo group.

Table 2: Adverse Reactions Occurring in ≥1% of Subjects in the CIMZIA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Studies PS-1, PS-2, and PS-3.

Adverse Reactions	CIMZIA 400 mg every other week n (%) N=342	CIMZIA 200 mg[5] every other week n (%) N=350	Placebo n (%) N=157
Upper respiratory tract infections[1]	75 (21.9)	68 (19.4)	33 (21.0)
Headache[2]	13 (3.8)	10 (2.9)	4 (2.5)
Injection site reactions[3]	11 (3.2)	6 (1.7)	1 (0.6)
Cough	11 (3.2)	4 (1.1)	3 (1.9)
Herpes infections[4]	5 (1.5)	5 (1.4)	2 (1.3)

1: Upper respiratory tract infection cluster includes upper respiratory tract infection, pharyngitis bacterial, pharyngitis streptococcal, upper respiratory tract infection bacterial, viral upper respiratory tract infection, viral pharyngitis, viral sinusitis, and nasopharyngitis.

2: Headache includes headache and tension headache.

3: Injection site reactions cluster includes injection site reaction, injection site erythema, injection site bruising, injection site discoloration, injection site pain, and injection site swelling.

4: Herpes infections cluster includes oral herpes, herpes dermatitis, herpes zoster, and herpes simplex.

5: Subjects received 400 mg of CIMZIA at Weeks 0, 2, and 4, followed by 200 mg every other week.

Elevated Liver Enzymes
Elevated liver enzymes were reported more frequently in the CIMZIA-treated subjects (4.3% in the 200 mg group and 2.3% in the 400 mg group) than in the placebo-treated subjects (2.5%). Of CIMZIA-treated subjects who had elevation of liver enzymes, two subjects were discontinued from the trial. In controlled Phase 3 studies of CIMZIA in adults with PsO with a controlled period duration ranging from 0 to 16 weeks, AST and/or ALT elevations ≥5 x ULN occurred in 0.9% of CIMZIA 200 mg or CIMZIA 400 mg arms and none in placebo arm.

Psoriasis-Related Adverse Events
In controlled clinical studies in psoriasis, change of plaque psoriasis into a different psoriasis sub-type (including erythrodermic, pustular and guttate), was observed in <1% of CIMZIA treated subjects.

Adverse Reactions of Special Interest Across Indications
Infections
The incidence of infections in controlled studies in Crohn's disease was 38% for CIMZIA-treated patients and 30% for placebo-treated patients. The infections consisted primarily of upper respiratory infections (20% for CIMZIA, 13% for placebo). The incidence of serious infections during the controlled clinical studies was 3% per patient-year for CIMZIA-treated patients and 1% for placebo-treated patients. Serious infections observed included bacterial and viral infections, pneumonia, and pyelonephritis.

The incidence of new cases of infections in controlled clinical studies in rheumatoid arthritis was 0.91 per patient-year for all CIMZIA-treated patients and 0.72 per patient-year for placebo-treated patients. The infections consisted primarily of upper respiratory tract infections, herpes infections, urinary tract infections, and lower respiratory tract infections. In the controlled rheumatoid arthritis studies, there were more new cases of serious infection adverse reactions in the CIMZIA treatment groups, compared to the placebo groups (0.06 per patient-year for all CIMZIA doses vs. 0.02 per patient-year for placebo). Rates of serious infections in the 200 mg every other week dose group were 0.06 per patient-year and in the 400 mg every 4 weeks dose group were 0.04 per patient-year. Serious infections included tuberculosis, pneumonia, cellulitis, and pyelonephritis. In the placebo group, no serious infection occurred in more than one subject. There is no evidence of increased risk of infections with continued exposure over time *[see Warnings and Precautions (5.1)]*.

In controlled clinical studies in psoriasis, the incidence rates of infections were similar in the CIMZIA and placebo groups. The infections consisted primarily of upper respiratory tract infections and viral infections (including herpes infections). Serious adverse events of infection occurred in CIMZIA-treated patients during the placebo-controlled periods of the pivotal studies (pneumonia, abdominal abscess, and hematoma infection) and Phase 2 study (urinary tract infection, gastroenteritis, and disseminated tuberculosis).

Tuberculosis and Opportunistic Infections
In completed and ongoing global clinical studies in all indications including 5,118 CIMZIA-treated patients, the overall rate of tuberculosis is approximately 0.61 per 100 patient-years across all indications.

The majority of cases occurred in countries with high endemic rates of TB. Reports include cases of disseminated (miliary, lymphatic, and peritoneal) as well as pulmonary TB. The median time to onset of TB for all patients exposed to CIMZIA across all indications was 345 days. In the studies with CIMZIA in RA, there were 36 cases of TB among 2,367 exposed patients, including some fatal cases. Rare cases of opportunistic infections have also been reported in these clinical trials. In Phase 2 and Phase 3 studies with CIMZIA in plaque psoriasis, there were 2 cases of TB among 1112 exposed patients *[see Warnings and Precautions]*.

Malignancies
In clinical studies of CIMZIA, the overall incidence rate of malignancies was similar for CIMZIA-treated and control patients. For some TNF blockers, more cases of malignancies have been observed among patients receiving those TNF blockers compared to control patients *[see Warnings and Precautions]*.

Heart Failure
In placebo-controlled and open-label studies, cases of new or worsening heart failure have been reported for CIMZIA-treated patients. The majority of these cases were mild to moderate and occurred during the first year of exposure *[see Warnings and Precautions]*.

Hypersensitivity Reactions
The following symptoms that could be compatible with hypersensitivity reactions have been reported rarely following CIMZIA administration to patients: angioedema, allergic dermatitis, dizziness (postural), dyspnea, hot flush, hypotension, injection site reactions, malaise, pyrexia, rash, serum sickness, and (vasovagal) syncope *[see Warnings and Precautions]*.

Autoantibodies
In clinical studies in Crohn's disease, 4% of patients treated with CIMZIA and 2% of patients treated with placebo that had negative baseline ANA titers developed positive titers during the studies. One of the 1,564 Crohn's disease patients treated with CIMZIA developed symptoms of a lupus-like syndrome.

In clinical trials of TNF blockers, including CIMZIA, in patients with RA, some patients have developed ANA. Four patients out of 2,367 patients treated with CIMZIA in RA clinical studies developed clinical signs suggestive of a lupus-like syndrome. The impact of long-term treatment with CIMZIA on the development of autoimmune diseases is unknown *[see Warnings and Precautions]*.

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

Patients with Crohn's disease were tested at multiple time points for antibodies to certolizumab pegol during Studies CD1 and CD2. In patients continuously exposed to CIMZIA, the overall percentage of patients who were antibody positive to CIMZIA on at least one occasion was 8%; approximately 6% were neutralizing *in vitro*. No apparent correlation of antibody development to adverse events or efficacy was observed. Patients treated with concomitant immunosuppressants had a lower rate of antibody development than patients not taking immunosuppressants at baseline (3% and 11%, respectively). The following adverse events were reported in Crohn's disease patients who were antibody-positive (N = 100) at an incidence at least 3% higher compared to antibody-negative patients (N = 1,242): abdominal pain, arthralgia, edema peripheral, erythema nodosum, injection site erythema, injection site pain, pain in extremity, and upper respiratory tract infection.

In two long-term (up to 7 years of exposure), open-label Crohn's disease studies, overall 23% (207/903) of patients developed antibodies against certolizumab pegol on at least one occasion. Of the 207 patients who were antibody positive, 152 (73%) had a persistent reduction of drug plasma concentration, which represents 17% (152/903) of the study population. The data from these two studies do not suggest an association between the development of antibodies and adverse events.

The overall percentage of patients with antibodies to certolizumab pegol detectable on at least one occasion was 7% (105 of 1,509) in the rheumatoid arthritis placebo-controlled trials. Approximately one third (3%, 39 of 1,509) of these patients had antibodies with neutralizing activity *in vitro*. Patients treated with concomitant immunosuppressants (MTX) had a lower rate of antibody development than patients not taking immunosuppressants at baseline. Patients treated with concomitant immunosuppressant therapy (MTX) in RA-I, RA-II, RA-III had a lower rate of neutralizing antibody formation overall than patients treated with CIMZIA monotherapy in RA-IV (2% vs. 8%). Both the loading dose of 400 mg every other week at Weeks 0, 2 and 4 and concomitant use of MTX were associated with reduced immunogenicity.

Antibody formation was associated with lowered drug plasma concentration and reduced efficacy. In patients receiving the recommended CIMZIA dosage of 200 mg every other week with concomitant MTX, the ACR20 response was lower among antibody-positive patients than among antibody-negative patients (Study RA-I, 48% versus 60%; Study RA-II 35% versus 59%, respectively). In Study RA-III, too few patients developed antibodies to allow for meaningful analysis of ACR20 response by antibody status. In Study RA-IV (monotherapy), the ACR20 response was 33% versus 56%, antibody-positive versus antibody-negative status, respectively *[see Clinical Pharmacology]*. No association was seen between antibody development and the development of adverse events.

Approximately 8% (22/265) and 19% (54/281) of subjects with psoriasis who received CIMZIA 400 mg every 2 weeks and CIMZIA 200 mg every 2 weeks for 48 weeks, respectively, developed antibodies to certolizumab pegol. Of the subjects who developed antibodies to certolizumab pegol, 45% (27/60) had antibodies that were classified as neutralizing. Antibody formation was associated with lowered drug plasma concentration and reduced efficacy.

A more sensitive and drug tolerant electrochemiluminescence (ECL)-based bridging assay was used for the first time in the nr-axSpA-1 study, resulting in a greater proportion of samples having measurable antibodies to certolizumab pegol and thus a greater incidence of patients being classed as antibody positive. In the placebo-controlled trial in patients with non-radiographic axial spondyloarthritis, after up to 52 weeks of treatment, the overall incidence of patients who were antibody positive to certolizumab pegol was 97% (248/255 patients). Of these antibody positive patients, higher titers were associated with reduced certolizumab pegol plasma levels.

The data above reflect the percentage of patients whose test results were considered positive for antibodies to certolizumab pegol in an ELISA, or ECL-based bridging assay, and are highly dependent on the sensitivity and specificity of the assay.

Postmarketing Experience
The following adverse reactions have been identified during post-approval use of CIMZIA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure.

Vascular disorder: systemic vasculitis has been identified during post-approval use of TNF blockers.

Skin: case of severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, and new or

worsening psoriasis (all sub-types including pustular and palmoplantar, and lichenoid skin reaction) have been identified during post-approval use of TNF blockers.

Immune System Disorders: sarcoidosis

Neoplasms benign, malignant and unspecified (including cysts and polyps): Melanoma, Merkel cell carcinoma (neuroendocrine carcinoma of the skin) *[see Warnings and Precautions]*.

DRUG INTERACTIONS

Use with Anakinra, Abatacept, Rituximab, and Natalizumab

An increased risk of serious infections has been seen in clinical studies of other TNF-blocking agents used in combination with anakinra or abatacept, with no added benefit. Formal drug interaction studies have not been performed with rituximab or natalizumab. Because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of CIMZIA in these combinations. There is not enough information to assess the safety and efficacy of such combination therapy. Therefore, the use of CIMZIA in combination with anakinra, abatacept, rituximab, or natalizumab is not recommended *[see Warnings and Precautions]*.

Live Vaccines

Avoid use of live (including attenuated) vaccines concurrently with CIMZIA *[see Warnings and Precautions]*.

Laboratory Tests

Interference with certain coagulation assays has been detected in patients treated with CIMZIA. Certolizumab pegol may cause erroneously elevated activated partial thromboplastin time (aPTT) assay results in patients without coagulation abnormalities. This effect has been observed with the PTT-Lupus Anticoagulant (LA) test and Standard Target Activated Partial Thromboplastin time (STA-PTT) Automate tests from Diagnostica Stago, and the HemosIL APTT-SP liquid and HemosIL lyophilized silica tests from Instrumentation Laboratories. Other aPTT assays may be affected as well. Interference with thrombin time (TT) and prothrombin time (PT) assays has not been observed. There is no evidence that CIMZIA therapy has an effect on *in vivo* coagulation.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to CIMZIA during pregnancy. For more information, healthcare providers or patients can contact:

MotherToBaby Pregnancy Studies conducted by the Organization of Teratology Information Specialists (OTIS). The OTIS AutoImmune Diseases Study at 1-877-311-8972 or visit http://mothertobaby.org/pregnancy-studies/

Risk Summary

Limited data from the ongoing pregnancy registry on use of CIMZIA in pregnant women are not sufficient to inform a risk of major birth defects or other adverse pregnancy outcomes. However, certolizumab pegol plasma concentrations obtained from two studies of CIMZIA use during the third trimester of pregnancy demonstrated that placental transfer of certolizumab pegol was negligible in most infants at birth, and low in other infants at birth *(see Data)*. There are risks to the mother and fetus associated with active rheumatoid arthritis or Crohn's disease. The theoretical risks of administration of live or live-attenuated vaccines to the infants exposed *in utero* to CIMZIA should be weighed against the benefits of vaccinations *(see Clinical Considerations)*. No adverse developmental effects were observed in animal reproduction studies during which pregnant rats were administered intravenously a rodent anti-murine TNFα pegylated Fab' fragment (cTN3 PF) similar to certolizumab pegol during organogenesis at up to 2.4 times the recommended human dose of 400 mg every four weeks.

The estimated 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 risks of major birth defects and miscarriage in clinically recognized pregnancies are 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data suggest that the risk of adverse pregnancy outcomes in women with rheumatoid arthritis or Crohn's disease is correlated with maternal disease activity and that active disease increases the risk of adverse pregnancy outcomes, including fetal loss, preterm delivery (before 37 weeks of gestation), low birth weight (less than 2500 g) and small for gestational age birth.

Fetal/Neonatal Adverse Reactions

Due to its inhibition of TNFα, CIMZIA administered during pregnancy could affect immune responses in the *in utero*-exposed newborn and infant. The clinical significance of BLQ or low levels is unknown for *in utero*-exposed infants. Additional data available from one exposed infant suggest that CIMZIA may be eliminated at a slower rate in infants than in adults *(see Data)*. The safety of administering live or live-attenuated vaccines in exposed infants is unknown.

Data

Human Data

A limited number of pregnancies have been reported in the ongoing pregnancy exposure registry. Due to the small number of CIMZIA-exposed pregnancies with known outcomes (n=54), no meaningful comparisons between the exposed group and control groups may be conducted to determine an association with CIMZIA and major birth defects or adverse pregnancy outcomes.

A multicenter clinical study was conducted in 16 women treated with CIMZIA at a maintenance dose of 200 mg every 2 weeks or 400 mg every 4 weeks during the third trimester of pregnancy for rheumatological diseases or Crohn's disease. The last dose of CIMZIA was given on average 11 days prior to delivery (range 1 to 27 days). Certolizumab pegol plasma concentrations were measured in samples from mothers and infants using an assay that can measure certolizumab pegol concentrations at or above 0.032 mcg/mL. Certolizumab pegol plasma concentrations measured in the mothers at delivery (range: 4.96 to 49.4 mcg/mL) were consistent with non-pregnant women's plasma concentrations in Study RA-I *[see Clinical Studies]*. Certolizumab pegol plasma concentrations were not measurable in 13 out of 15 infants at birth. The concentration of certolizumab pegol in one infant was 0.0422 mcg/mL at birth (infant/mother plasma ratio of 0.09%). In a second infant, delivered by emergency Caesarean section, the concentration was 0.485 mcg/mL (infant/mother plasma ratio of 4.49%). At Week 4 and Week 8, all 15 infants had no measurable concentrations. Among 16 exposed infants, one serious adverse reaction was reported in a neonate who was treated empirically with intravenous antibiotics due to an increased white blood cell count; blood cultures were negative. The certolizumab pegol plasma concentrations for this infant were not measurable at birth, Week 4, or Week 8.

In another clinical study conducted in 10 pregnant women with Crohn's disease treated with CIMZIA (400 mg every 4 weeks for every mother), certolizumab pegol concentrations were measured in maternal blood as well as in cord and infant blood at the day of birth with an assay that can measure concentrations at or above 0.41 mcg/mL. The last dose of CIMZIA was given on average 19 days prior to delivery (range 5 to 42 days). Plasma certolizumab pegol concentrations ranged from not measurable to 1.66 mcg/mL in cord blood and 1.58 mcg/mL in infant blood; and ranged from 1.87 to 59.57 mcg/mL in maternal blood. Plasma certolizumab pegol concentrations were lower (by at least 75%) in the infants than in mothers suggesting low placental transfer of certolizumab pegol. In one infant, the plasma certolizumab pegol concentration declined from 1.02 to 0.84 mcg/mL over 4 weeks suggesting that certolizumab pegol may be eliminated at a slower rate in infants than adults.

Animal Data

Because certolizumab pegol does not cross-react with mouse or rat TNFα, reproduction studies were performed in rats using a rodent anti-murine TNFα pegylated Fab' fragment (cTN3 PF) similar to certolizumab pegol. Animal reproduction studies have been performed in rats during organogenesis at intravenous doses up to 100 mg/kg (about 2.4 times the recommended human dose of 400 mg, based on the surface area) and have revealed no evidence of harm to the fetus due to cTN3 PF.

Lactation

Risk Summary

In a multicenter clinical study of 17 lactating women treated with CIMZIA at 200 mg every 2 weeks or 400 mg every 4 weeks, minimal certolizumab pegol concentrations were observed in breast milk. No serious adverse reactions were noted in the 17 infants in the study. There are no data on the effects on milk production. In a separate study, certolizumab pegol concentrations were not detected in the plasma of 9 breastfed infants at 4 weeks post-partum *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CIMZIA and any potential adverse effects on the breastfed infant from CIMZIA or from the underlying maternal condition.

Data

A multicenter clinical study designed to evaluate breast milk was conducted in 17 lactating women who were at least 6 weeks post-partum and had received at least 3 consecutive doses of CIMZIA 200 mg every 2 weeks or 400 mg every 4 weeks for rheumatological disease or Crohn's disease. The effects of certolizumab pegol on milk production were not studied. The concentration of certolizumab pegol in breast milk was not measurable in 77 (56 %) of the 137 samples taken over the dosing periods using an assay that can measure certolizumab pegol concentrations at or above 0.032 mcg/mL. The median of the estimated average daily infant doses was 0.0035 mg/kg/day (range: 0 to 0.01 mg/kg/day). The percentage of the maternal dose (200 mg CIMZIA dosed once every 2 weeks), that reaches an infant ranged from 0.56% to 4.25% based on samples with measurable certolizumab pegol concentration. No serious adverse reactions were noted in the 17 breastfed infants in the study.

In a separate study, plasma certolizumab pegol concentrations were collected 4 weeks after birth in 9 breastfed infants whose mothers had been currently taking CIMZIA (regardless of being exclusively breastfed or not). Certolizumab pegol in infant plasma was not measurable i.e., below 0.032 mcg/mL.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Due to its inhibition of TNFα, CIMZIA administered during pregnancy could affect immune responses in the *in utero*-exposed newborn and infant *[see Use in Specific Populations)]*.

Geriatric Use

Clinical studies of CIMZIA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Population pharmacokinetic analyses of patients enrolled in CIMZIA clinical studies concluded that there was no apparent difference in drug concentration regardless of age. Because there is a higher incidence of infections in the elderly population in general, use caution when treating the elderly with CIMZIA *[see Warnings and Precautions]*.

OVERDOSAGE

The maximum tolerated dose of certolizumab pegol has not been established. Doses of up to 800 mg subcutaneous and 20 mg/kg intravenous have been administered without evidence of dose-limiting toxicities. In cases of overdosage, it is recommended that patients be monitored closely for any adverse reactions or effects, and appropriate symptomatic treatment instituted immediately.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide)

Risk of Serious Infections

Inform patients that CIMZIA may lower the ability of the immune system to fight infections. Instruct patients of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections. Because caution should be exercised in prescribing CIMZIA to patients with clinically important active infections, advise patients of the importance of informing their health care providers about all aspects of their health *[see Warnings and Precautions]*.

Malignancies

Counsel patients about the possible risk of lymphoma and other malignancies while receiving CIMZIA *[see Warnings and Precautions]*.

Other Medical Conditions

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report promptly any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever *[see Warnings and Precautions]*.

Hypersensitivity Reactions

Advise patients to seek immediate medical attention if they experience any symptoms of severe hypersensitivity reactions. Advise latex-sensitive patients that the needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex *[see Warnings and Precautions]*.

Pregnancy

Advise patients that there is a pregnancy registry that monitors pregnancy outcomes in women exposed to CIMZIA during pregnancy; patients can call 1-877-311-8972 *[see Use in Specific Populations]*.

Preparation and Administration of CIMZIA Using the Prefilled Syringe

Instruct patients and caregivers on how to inject the Prefilled Syringe. Complete instructions are provided in the Instructions for Use packaged in each CIMZIA Prefilled Syringe kit.

Product manufactured by:
UCB, Inc.,1950 Lake Park Drive, Smyrna, GA 30080
US License No. 1736
For more information, go to www.CIMZIA.com or call 1-866-424-6942.
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FINANCIAL CONSIDERATIONS UNIQUE TO U.S. PHYSICIANS

Simple Steps for Early Action

ANDREW HARMS AND MIRIAM SWEENEY

For the average U.S. household, everyday living is getting pricey. Childcare, food, energy, transportation, and housing costs are all rising. Among U.S. physicians and healthcare professionals, personal financial matters may make things tougher given high educational debt-loads, capped income levels during residency years, and unique insurance needs. Furthermore, job-related stressors emanating from clinical and patient-care priorities, administrative duties, continuing education, licensing requirements, and professional responsibilities leave little time for prudent, active personal financial management.

Self-reported depression and burnout rates are high. In fact, in recent years more than 4 in 10 U.S. physicians report feeling burned out.[1] When asked to rate factors that contribute to depression, results from Medscape's annual National Physician Lifestyle Report indicate personal finances ranked second to job/workplace as a contributing factor.[2]

When asked what would reduce their burnout, the number one response from physicians (roughly a third) indicated the best way to combat burnout would be increased financial compensation. We want to be paid more. In fact, more money was a more common response than a more manageable schedule.

The circumstances facing a physician's personal finances present a unique challenge to most in medicine, regardless of specialty. A predominant factor to financial troubles for physicians includes the high cost of education required to become a physician.

According to the AMA, one in four medical students graduates with training-related debt that exceeds $200,000, and half of medical school graduates report debt burdens greater than $150,000. Those financial burdens are combined with a demanding schedule during graduate medical education and can affect well-being for physician residents and fellows. "Between financial restraints and 80-hour workweeks, trainees often struggle with having the time and budget for necessities. When residency and fellowship programs provide benefits to assist with these needs, it can significantly improve trainee well-being," said AMA Trustee Jesse Ehrenfeld, MD, MPH.[3]

Compounding the difficulties, we recognize that the time and attention required to study medicine, biological sciences, and patient care during training to become a physician leaves little room to acquire a solid education in personal financial management.

Prioritizing personal financial literacy for early-career physicians

Many physicians have access to financial resources early on in their career, but that doesn't mean they're confident about their financial situation. At the medical school level, some hopeful trends have emerged to address the rising educational debt levels burdening many graduates.

At a handful of US medical schools, financial aid offices have transitioned to financial wellness offices—aiming to better help students with personal financial understanding, housing and living expense considerations, etc.—moving beyond simply providing tuition financing guidance in order to provide holistic financial support and literacy. A great example of this is witnessed at the University of Arkansas for Medical Sciences, where Jason Mizell, M.D., and UAMS faculty have facilitated a popular 'Business of Medicine' course since 2012, taught to residents and fourth-year medical students.[4] This course serves to teach early-stage physicians both practice management finance (coding, billing, malpractice, etc.) and, very importantly, personal finance.

Another excellent example of an offering available to medical students is provided by the University of Wisconsin School of Medicine and Public Health. When medical student Rufus Sweeney struck up conversations with his peers some years ago about their personal finances, he was shocked by how few understood their student debt or even knew about options to pay it off. With a grant from the Wisconsin Medical Society, Rufus joined with Emma Crawford, UW SMPH Director of Financial Wellness and Financial Aid Advising, to develop UW-Madison SMPH's first ever course focused on physician personal finance. This course continues and remains the most popular elective credit offering at the medical school.

While such personal finance educational initiatives exemplified by UAMS and UW-Madison go a long way to improving financial literacy for young physicians, the trend to educate and empower physicians in the way of personal finances should be prioritized in order to meet cost of living challenges and resultant burnout rates. An introduction to personal finance is a great offering at the medical school level, and—if followed on with subsequent support at each next stage of a physician's career—would provide a proper runway to financial health and wellness.

At the residency level, new expenditure considerations often outweigh the long-awaited first paycheck. Many times, newly minted residents find themselves unprepared to manage a tight budget. A resident may sometimes find financial resources made available as a new employee helpful—though the quality and availability of personal financial support is disparate and often inadequate. While the financial picture of a resident includes income, the AMA clearly points out the following: "It takes years to realize your earning potential. As a physician, you will not maximize your earnings until the completion of your graduate medical education. The average first-year resident makes around $60,000, (2018 report) and there's not much wiggle room.

Resident salaries are determined by an institution and correlate with training year rather than specialty. So, in a given training institution, all residents who are in their third year of training get the same salary, and all in their sixth year are paid the same."[5]

Given the ceiling on income, how many physicians at the resident level have developed the experience and skills to single handedly manage the new challenges to their budget which may stem from debt-repayment, insurance needs, retirement

saving, and other important considerations?

Factoring in time constraints and the reasonable desire for a personal life, very few residents have the time to dedicate to getting a handle on personal finances. A host of negative consequences may arise if physicians make financial mistakes at these early stages.

Self-reported depression and burnout rates are high. In fact, in recent years **MORE THAN 4 IN 10 U.S.**

Where to start? Where to turn for help? Start simply.

Financial health should be treated in a similar way to attending to physical and mental health. When viewed from this perspective, the training of physicians gives this occupational group an advantage when tackling personal finances.

Let's outline some simple steps early-career physicians can take to prepare for a healthier financial future:

BECOME FAMILIAR WITH YOUR FINANCIAL VITAL SIGNS

While carving out time from a busy schedule may seem impossible, scheduling a bit of time to learn some basics about your individual circumstances is essential. Dedicate some time—think about this as you would think about making an appointment with a doctor. Put it on your calendar.

Begin with some basic information gathering: Identify all sources of household income (review your paychecks, line by line); identify your fixed monthly expenses (housing payments, childcare costs, set-aside contributions for savings, etc.), as well as your variable monthly expenses (utilities, subscription services, transportation costs, etc.). As in most things in life, the best first step is figuring out where you are.

CONSTRUCT A MONTHLY BUDGET

You may think of this step as you would a treatment regimen. Crafting a monthly financial plan that identifies each incoming dollar and prudently purposes each outgoing dollar will provide a way forward and likely reduce the mental burden of financial unknowns. There are many good budgeting templates and guides. Like finding a good primary care physician, find yourself a budget that you like and works well for you. And like any treatment regimen, stick to your budget in order to achieve good health.

KNOW YOUR DEBT REPAYMENT OPTIONS

For the majority of physicians, this step is vital to understand and implement. One resource worth checking out is provided by Doctored Money[6] , a non-profit serving physicians that has wonderful debt repayment tools and calculators.

IDENTIFY SUPPORT AND ESTABLISH COMMUNICATION

Assess your surroundings to locate trustworthy financial resources and fiduciary support, if needed. In many cases, the institution with which you are affiliated may have personal financial resources offered. Take advantage of these opportunities when available, if nothing else than to better educate yourself. Once you've built a network of professionals with whom you can confide, communicate to them as you would with your PCP, remembering that your goal is to limit risks and improve your overall health.

CONDUCT ROUTINE FINANCIAL CHECK-UPS

Living within a smartly formulated monthly budget is a winning health strategy, and combined with periodic (quarterly, semi-annual, annual) reviews of your financial vitals will increase your ability to achieve your financial goals. Schedule these reviews on your calendar well in advance, and approach them as you would a visit to any healthcare specialist. Satisfied debts, cost of living adjustments, salary increases, unexpected expenses, changes in the investable landscape, and other life events will prompt adjustments to your monthly budget. Regular check-ups will help you recognize and appropriately transition your personal finances. Utilize your network of resources and professional support on a regularly scheduled basis.

We've been talking a lot about early-career physician groups, but our suggestions are applicable to most, if not all, readers.

Address your financial needs with consistency, and in spite of uncertainties facing the cost of goods and households, we'll make the U.S. healthcare system a secure, confident foundation for personal and community growth.

RESOURCES

1. Medscape National Physician Burnout & Suicide Report 2020: The Generational Divide
2. Medscape National Physician Burnout & Depression Report 2018
3. https://www.ama-assn.org/residents-students/resident-student-health/resident-physicians-should-get-help-shoulder-financial
4. Business of Medicine Course Preps Med Students for Real World | UAMS News
5. 6 things medical students should know about physician compensation | American Medical Association (ama-assn.org)
6. Doctored Money

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