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THE LATEST ON

INFLAMMATORY BOWEL DISEASE

WRITTEN IN YOUR GENES

A new study underscores the need for representation in genetics research. Scientists looked at whether 25 rare gene mutations known to raise risk for inflammatory bowel disease (IBD) in White European people are also present in Black people. They found that these variants are extremely rare in Black people and that those who do carry them also show genetic signs of some degree of European ancestry. The study demonstrates that these rare gene variants were introduced into the Black population by White Europeans, and it emphasizes the urgent need to research rare disease-specific gene variants in people of all backgrounds, not just a White European background.

SOURCE: Genome Medicine

15 to 30 Most common ages at which IBD is diagnosed.

SOURCE: National Library of Medicine

1.9 million

Number of U.S. adults who have ulcerative colitis.

SOURCE: Preventive Medicine Reports

A NOT-SO-SWEET DISCOVERY

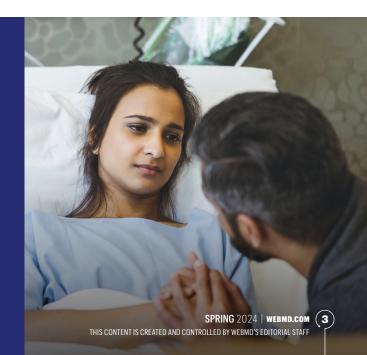
Researchers might have discovered why sugar keeps some people flared up. A normal large intestine, or colon, sheds its lining and generates a new one every 5 days. Any damaged or inflamed cells are lost and replaced with healthy new ones. Scientists looked at this intestinal lining in mice with IBD. When they fed the mice an extremely high-sugar diet, they found that the colon's process of regenerating itself every few days was shut down. Sugar also stunted cell growth in human colon tissue in a lab. The discovery could explain why sweets trigger flares.

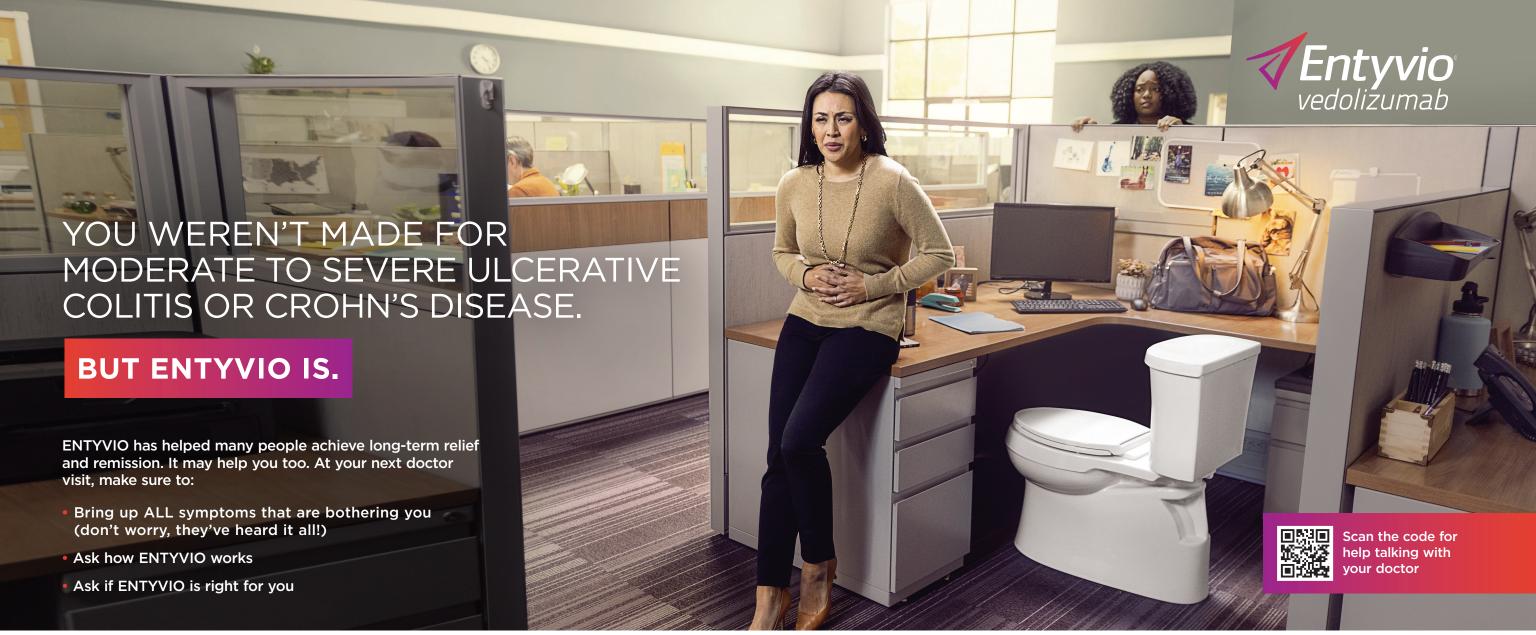
SOURCE: Cellular and Molecular Gastroenterology and Hepatology

HEALING IS THE GOAL

When your inflammatory bowel disease is active, you're at risk for serious infections that require a hospital stay. Doctors tended to believe this risk came mainly with highly active disease. But new research suggests that you're not fully out of the woods until your intestine is completely healed. In a study of 55,626 people with IBD, researchers found that even when you have areas of microscopic inflammation—that is, low disease activity—you are still nearly twice as likely to need to go to the hospital for an infection as you are when your intestine is healed. Effective IBD treatment can help avoid this risk.

SOURCE: Clinical Gastroenterology and Hepatology





Important Safety Information for ENTYVIO® (vedolizumab)

- Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of its ingredients.
- ENTYVIO may cause serious side effects, including:
- o Infusion-related and serious allergic reactions can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get immediate medical help if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).
- ENTYVIO may increase your risk of getting a serious infection. Before receiving and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or symptoms of an infection, such as fever, chills.

- muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.
- o People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision.
- Liver problems can happen in people who receive ENTYVIO. Tell your healthcare provider right away if you have any of the following symptoms: tiredness, loss of appetite, pain on the right side of your abdomen, dark urine, or yellowing of the skin and eyes (jaundice).

- The most common side effects of ENTYVIO include common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in extremities. These are not all the possible side effects of ENTYVIO. Call your healthcare provider for medical advice about side effects.
- Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you: have or think you may have an infection or have infections that keep coming back; have liver problems; have tuberculosis (TB) or have been in close contact with someone with TB; have recently received or are scheduled to receive a vaccine; or if you are pregnant, breastfeeding, plan to become pregnant, or plan to breastfeed.

Please see the Important Facts for ENTYVIO on the following page and talk with your healthcare provider.

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.

Uses of ENTYVIO® (vedolizumab)

ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn's disease



ENTYVIO is a trademark of Millennium Pharmaceuticals, Inc., registered with the U.S. Patent and Trademark Office and is used under license by Takeda Pharmaceuticals U.S.A., Inc.

IMPORTANT FACTS

ENTYVIO (en ti' vee oh) (vedolizumab) for injection, for intravenous use

What is the most important information I should know about ENTYVIO?

ENTYVIO may cause serious side effects, including:

- Infusion-related and serious allergic reactions. These reactions can happen while you are receiving ENTYVIO or several hours after treatment. You may need treatment if you have an allergic reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an infusion of ENTYVIO: rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing).
- Infections. ENTYVIO may increase your risk of getting a serious infection. Before receiving ENTYVIO and during treatment with ENTYVIO, tell your healthcare provider if you think you have an infection or have symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.
- Progressive Multifocal Leukoencephalopathy (PML). People with weakened immune systems can get progressive multifocal leukoencephalopathy (PML) (a rare, serious brain infection caused by a virus). Although unlikely while receiving ENTYVIO, a risk of PML cannot be ruled out. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. Tell your healthcare provider right away if you have any of the following symptoms: confusion or problems thinking, loss of balance, change in the way you walk or talk, decreased strength or weakness on one side of the body, blurred vision, or loss of vision.
- Liver Problems. Liver problems can happen in people who
 receive ENTYVIO. Tell your healthcare provider right away if
 you have any of the following symptoms: tiredness, loss of
 appetite, pain on the right side of your stomach (abdomen),
 dark urine, or yellowing of the skin and eyes (jaundice).

See "What are the possible side effects of ENTYVIO?" for more information about side effects.

What is ENTYVIO?

ENTYVIO is a prescription medicine used in adults for the treatment of:

- moderately to severely active ulcerative colitis.
- moderately to severely active Crohn's disease.

It is not known if ENTYVIO is safe and effective in children under 18 years of age.

Who should not receive ENTYVIO?

Do not receive ENTYVIO if you have had an allergic reaction to ENTYVIO or any of the ingredients in ENTYVIO. See the end of this Medication Guide for a complete list of ingredients in ENTYVIO.

Before receiving ENTYVIO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection, think you may have an infection or have infections that keep coming back (see "What is the most important information I should know about ENTYVIO?").
- have liver problems.

- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive a vaccine.
 Talk to your healthcare provider about bringing your vaccines up-to-date before starting treatment with ENTYVIO.
- are pregnant or plan to become pregnant. It is not known if ENTYVIO will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ENTYVIO.
 - Pregnancy Registry: There is a pregnancy registry for women who use ENTYVIO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry or you may contact the registry at 1-877-825-3327 to enroll.
- are breastfeeding or plan to breastfeed. ENTYVIO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ENTYVIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your healthcare provider if you take or have recently taken Tysabri (natalizumab), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

How will I receive ENTYVIO?

- ENTYVIO is given through a needle placed in a vein (intravenous infusion) in your arm.
- ENTYVIO is given to you over a period of about 30 minutes.
- Your healthcare provider will monitor you during and after the ENTYVIO infusion for side effects to see if you have a reaction to the treatment.

What are the possible side effects of ENTYVIO?

ENTYVIO may cause serious side effects, see "What is the most important information I should know about ENTYVIO?".

The most common side effects of ENTYVIO include: common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in extremities.

These are not all of the possible side effects of ENTYVIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about ENTYVIO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about ENTYVIO that is written for health professionals.

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For more information, go to www.ENTYVIO.com or call 1-877-TAKEDA-7 (1-877-825-3327).

STATS & FACTS

By Sonya Collins

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

TO 3 in

Number of people with IBD who don't get help from the first treatment they try.

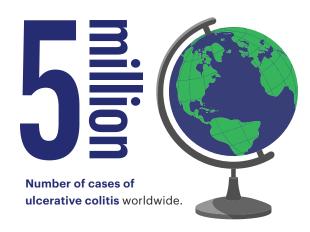


Number of U.S. adults who have a diagnosis of IBD.

Number of new cases of IBD diagnosed in the U.S.

every year.





Number of people with IBD whose treatment stops working over time.





How many more White people have IBD than Black, Asian, or Hispanic people.



Number of people in the U.S. with Crohn's disease.

SOURCES: Preventive Medicine Reports, International Journal of Molecular Sciences, Gastroenterology, The Lancet, Medicape

SIGNS IT'S TIME FOR A TREATMENT CHANGE

HOW TO KNOW YOUR MEDICATION ISN'T WORKING ANYMORE

By Rachel Reiff Ellis Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

The goal of IBD treatment is straightforward: to reduce inflammation in your intestinal lining, which will reduce your symptoms and prevent complications of the disease. When your treatment isn't achieving that goal or you're having side effects you can't tolerate, it may be time to try something new.

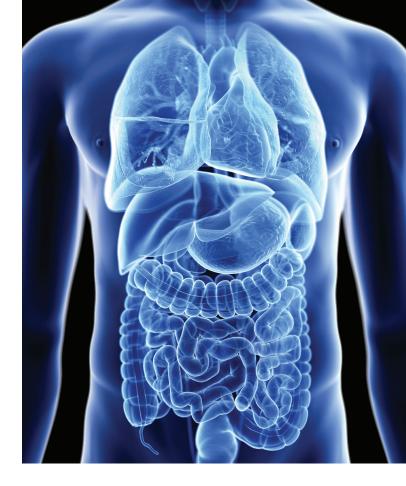
"It's a little bit of trial and error," says Sumona Saha, MD, a gastroenterologist at UW Health in Madison, WI, who specializes in inflammatory bowel disease. "Even with some of our best therapies, which we consider to be the biologics and small molecules, there's a sizable number of patients who don't respond."

If a medication doesn't work from the beginning, that's called primary nonresponse, Saha says. Secondary nonresponse means a medication worked for a while but eventually stops.

WHAT DOCTORS LOOK FOR

Well-controlled IBD goes beyond absence of symptoms. Your doctor will need to perform tests to see how your intestinal lining is faring.

"We're moving more toward 'treat to target endpoint,' which means we go beyond symptom improvement to look at improvement in some objective markers of inflammation," Saha says.



The way they do this includes having a colonoscopy, biopsy, and a noninvasive test called fecal calprotectin, which looks for inflammation in your stool.

"We look to see if we've achieved what we call mucosal healing, which is improvement in the appearance of the intestinal lining, both as we see it with our naked eye, using the camera, and as well as when we look at the tissue underneath the microscope," Saha says.

INFLAMMATION CHECK TIMING

How often does your doctor need to look for these signs of inflammation to keep you on track? That depends, says Saha.

"If you're starting a new therapy, then we typically will do this type of assessment after you complete what we call induction therapy or the loading doses to see if you have kind of the response that we're looking for," Saha says.

If you're in the maintenance phase of your treatment—therapy that's been working for you—then it's up to your doctor how often they check your inflammation markers.

"There aren't definite guidelines for testing, like every 6 months or once a year," Saha says. "It's more at the discretion of the provider."

CHECK IN EARLY AND OFTEN

The key to good IBD care is to head off intestinal damage before it gets bad. Keep your doctors in the loop if anything seems off between checkups.

"We want to know about things early, not when they're already bad," Saha says. "If we recognize it early, then we can do the medication adjustment and recapture that remission."

WHEN YOU DON'T

TREAT IBD

RISKS AND COMPLICATIONS OF LEAVING YOUR DISEASE UNTREATED

By Rachel Reiff Ellis

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

Managing your Crohn's disease or ulcerative colitis well means treating the disease under the care of a doctor. When you don't treat the underlying inflammation of the disease, you increase the number of flare-ups you have, raise the risk of complications, and can progress your disease toward irreversible damage of your bowel.

"The longer you let these conditions go without treating them, the harder they can become to treat," says Erica R. Cohen, MD, inflammatory bowel disease specialist at Capital Digestive Care in Chevy Chase, MD. "It's one of the most common issues I see-lack of treatment that leads to a progression of the illness to something that could have been stopped or controlled at an earlier phase."

PROGRESSION OF THE DISEASE

When it gets severe, IBD inflammation can go several layers deep in the bowel, causing problems such as perianal fistulas.

"These are tunnels that lead from the end of the bowel to the anus, and they cause pain, redness, swelling, and drainage," Cohen says. You may also get chills, feel tired, or generally unwell when you have them.

You can also develop strictures, which narrow your intestinal wall and may eventually obstruct your bowel, meaning nothing can get through.

One problem that can happen when ulcerative colitis spreads to deeper layers of the bowel is toxic megacolon, which can lead to life-threatening infections, kidney failure, or a colon rupture. A doctor needs to treat this immediately-and you may need surgery that permanently changes your bowel.

You may also find yourself getting sick more often if your IBD progresses because your immune system



is working overtime to help keep the inflammation under

"It puts constant stress on your body, which makes you vulnerable to infections and other illnesses," Cohen says.

INCREASED CHANCE OF COMPLICATIONS

While complications of IBD are possible for anyone with the disease, it's much more likely if you're not treating the damaging inflammation caused by the condition. The complications you can get depend on where the inflammation is in your digestive tract.

"IBD effects can go beyond the gut and cause what we call extraintestinal manifestations of the disease," Cohen says. Some of the most common include:

- Arthritis
- · Skin conditions
- · Inflammation of the eyes
- · Liver disorders
- Kidney disorders
- Bone loss

Your risk of colorectal cancer goes up, too.

"The cells in the lining of the colon constantly turn over in an effort to repair the damage, which increases the chances that a mutation can happen," Cohen says.

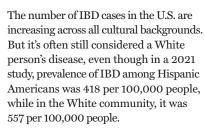
Your best prevention against these problems is to get on and stay on treatment for your disease.

THE HISPANIC **POPULATION AND IBD**

WHAT TO KNOW ABOUT LIVING WITH AND TREATING YOUR CONDITION

By Rachel Reiff Ellis

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor



The Hispanic community also faces unique issues when it comes to the disease.

IDENTIFYING THE DISEASE

"There's a bigger delay in IBD diagnosis for Hispanics," says Joanna Lopez, MD, gastroenterologist at Gastro Health in Miami, FL. "Hispanic patients are not the typical patient population that we think of when we think of inflammatory bowel disease, so for a lot of providers, it doesn't come to mind first in a differential diagnosis."

This delay in diagnosis happens even more often for Hispanic people born outside of the U.S., Lopez says.

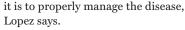
"They may not seek care, they may not have insurance, or they may have barriers because of their language, so communication with the providers may not express exactly what their symptoms are," Lopez says. "There are many reasons why the delay may happen."

One of the big barriers that's not unique to the Hispanic population but certainly impacts it is the reluctance to open up about bowel symptoms.

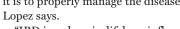
"There is definitely a lot of hesitation and embarrassment to discuss symptoms that relate to bowel movements including bleeding and incontinence, and sometimes impact sexual health, across all populations and maybe more so in the Hispanic community," says Siddharth Singh, MD, gastroenterologist at UC San Diego Health in California.

THE EFFECTS OF DELAYED DIAGNOSIS

The longer it takes to get a diagnosis and start treatment, the higher the risk of complications and the more difficult



"IBD is a chronic, lifelong inflammatory condition that affects the intestinal system, and it requires lifelong management, with proper management to be done from the very



SIGNS OF IBD

Siddharth Singh, MD, says to be vigilant of these symptoms:

- + Diarrhea
- + Abdominal pain
- + Blood in your stool
- + Pooping more than usual
- + Needing to poop urgently



beginning," Lopez says. "So the longer patients have undiagnosed disease, usually the more complicated and advanced they are once they are diagnosed and the harder it may be to treat."

Hispanic people with delayed diagnosis are at greater risk of strictures (areas where the bowel narrows due to scarring), fistulas (a passage between organs or nearby tissues that isn't normally there), abscesses (an infection that may result in a fistula if not treated), and cancer of the bowel.

Many of these can be avoided easily with prompt treatment, which is why it's important to increase the awareness of the disease in the Hispanic community and those who treat them.

OVERCOMING BARRIERS

Both Singh and Lopez agree that having a strong relationship with your gastroenterologist is key to good disease management.

Lopez says she recommends seeing an IBD specialist, although she notes that it's not always possible depending on where you live and insurance limitations. Still, if possible, it can help you have a better outcome and tighter control of the disease.

"At least once a year or every couple of years, see an inflammatory bowel disease doctor," Lopez says. "If that's somebody who is also fluent in your language and culturally sensitive to your background, even better."

Singh is hopeful that with more awareness, an increase in diversity of providers, and technology that helps bridge language barriers, people across all cultures will have quicker diagnoses and better outcomes.

"There should be no fear or embarrassment about this disease," Singh says. "Treatment has evolved tremendously over the last 2 decades, and most people with IBD live a long and fulfilling life."

RESOURCES TO HELP

These specific sites can be a support on your journey.

- + Crohn's & Colitis Foundation (CrohnsColitisFoundation.org/es) provides disease information and support in Spanish.
- + Color of Gastrointestinal Illnesses (ColorOfGl.org) offers community, education, and advocacy opportunities for people of color living with digestive disorders.

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MY LIFE WITH **CROHN'S** DISFASF

ALTHOUGH I HAVE BAD DAYS, THERE IS HOPE

By Jennifer Al-Amin

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

I went on my first cruise recently and I was so nervous. I've lived with Crohn's for years, but I'm still anxious when I'm in new places. For me, preparation has been the key.

MY LOW MOMENTS

Before my 30th birthday and when my daughters were young, I had issues with my stomach. I took a week off work and had all kinds of tests. I couldn't eat anything. I had shooting pain in my side, and I just lived with it for years. I would work, come home and make dinner, get the kids to sleep, and crash. (My husband worked the second shift.) I would map my way to work knowing where the bathrooms and gas stations were.

My worst day was going to a holiday party with friends, and I asked them to pull over so I could relieve myself. They gave me toilet tissue for a birthday one year. They made it lighthearted, but this was my life, and it was hard.

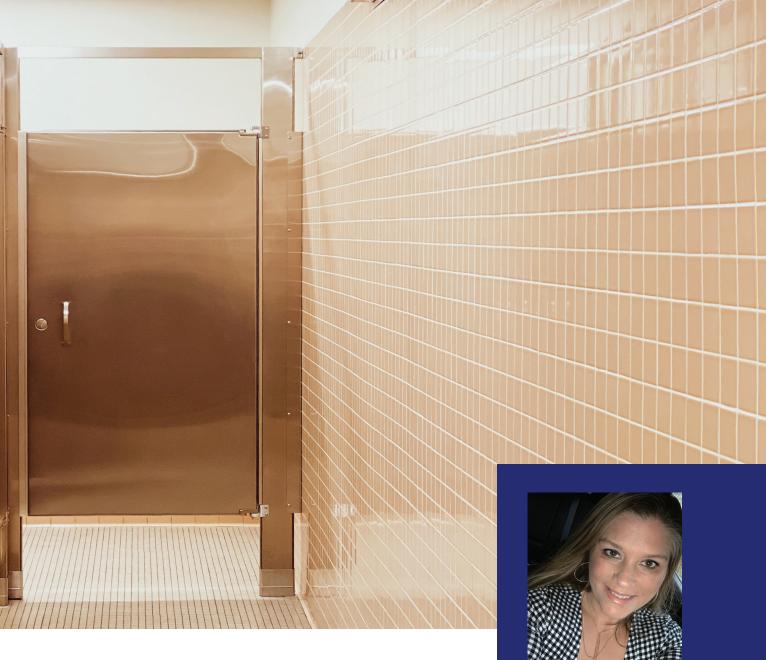
FINALLY. AN ANSWER

Once I went to the ER after throwing up for days, losing 7 pounds in a week, and feeling terrible. They did a CT scan and said, "You have Crohn's. It's an issue and



you need to see a gastro doctor." This doctor confirmed my diagnosis and put me on steroids for the inflammation. That helped a bit, but I couldn't keep the steroids down. Soon after, I had bowel surgery.

I had to help my family and friends understand that I wasn't just being dramatic. When I need to use the bathroom, it's serious. I've gone into stores where they say the bathroom is just for employees or that I must buy something before I can use the restroom. I think there should be more awareness about people with digestive issues who need access to a restroom. I have towels, a change of clothes, and bottled water to keep me hydrated in my car.



MOVING FORWARD

My doctors have great hope in biologics for me. I'm hoping to start a new medication soon that seems promising. As I work through different options, I try to focus on things I can do. I cook most of my meals at home. I try not to eat spicy foods or anything I know won't work well for my digestive system. I try to keep stress down. And I prefer to drive when I'm going somewhere. This way, I don't feel awkward if I need to make a stop. When my mom comes to visit, she hands the car keys over to me immediately.

My family understands a lot more now. My daughters bring me cold

compresses when I'm having a flare. I'm used to going to the ER from time to time and will advise them that I need an IV, pain medications, and a CT scan. I know that depending on the results of my CT, I might have to be there for a few days.

I have bad days, but spending time with my husband (my high school sweetheart), my five daughters, and my grandkids keeps me going. I love concerts and traveling. There is life with Crohn's. It's helped me to add structure to my life. I may not be able to be as spontaneous, but there is life. There is hope.

JENNIFER'S TIPS

- + Get a support system in place. Find people who are also dealing with Crohn's.
- + Take care of you. If you wear yourself down, it won't help.
- + Be prepared. You don't want to be caught off-quard.

FINDING EMOTIONAL AND FINANCIAL SUPPORT

EASING THE STRESS MAY HELP YOU FEEL BETTER, TOO

By Kendall K. Morgan

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

Crohn's disease and ulcerative colitis (UC) aren't only hard on your gut. They can also take a toll on your emotions. The care you'll need for your chronic condition can put a serious strain on your wallet, too. People with Crohn's or UC often experience financial distress. The stress from the emotional and financial burdens may make your gut symptoms worse. That's why specialized IBD treatment centers often include psychosocial care, says Laurie A. Keefer, PhD, a health psychologist at Mount Sinai in New York City.

"When you have gut symptoms, fear and anxiety can keep you from leaving your house," Keefer says. "You can feel isolated. ... When you're under a lot of stress, you may find your IBD acts up more. It's that cyclical situation between the brain and gut working together."

MIND AND BODY

How well you'll do medically and physically depend in part on how you manage your condition emotionally, Keefer says. When you're down or depressed, you may be less likely to go pick up your medicine from the pharmacy or schedule that colonoscopy. If you have a mental health condition as well as Crohn's or UC, you'll want to make sure you're treating it, too, Keefer says.

Even if you haven't been diagnosed with a mental health condition, you may still find it tough to accept your gut condition and to face it with hope and optimism, Keefer says. Her advice: Look for supports that can help you with the aspects of your condition you find hard, whether it's swallowing pills, dealing with your health insurance company, or something else.

"When you build confidence and resilience, you can actually prevent the onset of depression, anxiety, and medical trauma," Keefer says.





TACKLING FINANCIAL STRAIN

In addition to managing your emotions, you'll also need to handle any financial concerns you have. Most people with Crohn's or UC have worries about finances and insurance coverage, says Cassie Ray, director of advocacy for the Crohn's & Colitis Foundation in New York City.

It helps to understand your insurance coverage plan and make sure your doctor is "in network." If you or your partner work for a company that has a human resources (HR) department, Ray recommends asking HR if they have an insurance navigator. If you don't have health insurance, talk to a social worker or someone who can help you get set up with public or private health insurance. In addition to insurance, there are assistance programs to help with treatment or other costs, whether it's through your hospital or clinic, a charitable organization, or pharmaceutical company.

Ray recommends calling the Crohn's & Colitis Foundation's IBD Help Center at 888-694-8872 and selecting option 8 from the phone menu for advice and help connecting with resources. Keep in mind that insurance companies often deny claims the first time, especially for prescribed biologics, Ray says. It may take multiple appeals, but she says those medications often get covered eventually.

"Be persistent; be patient," Ray says. "It can be difficult when you're stressed with illness and now have to work to find a way to cover treatment, but your health is worth it."

SEEK SUPPORT

Along with your doctors, these pros may help:

- + Psychologists
- + Pharmacists
- + Dietitians
- + Social workers
- + Assistance programs
- + Information specialists
- + Support groups



Find a Restroom, FAST: We Can't Wait Restroom App



Anyone can find a public restroom quickly and easily with the **We Can't Wait** app from the Crohn's & Colitis Foundation. Whether you are an IBD patient or just need a restroom fast, this new app makes it easy to find a bathroom wherever you are!

We Can't Wait features a database of over 55,000 public restrooms nationwide, and over 3,000 verified partner establishments. Download free on the App Store[®] or Google Play.[™]

Learn more about the We Can't Wait App and the Foundation's Open Restrooms Movement: crohnscolitisfoundation.org/openrestrooms

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