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INFLAMMATORY BOWEL DISEASE

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GET ON THE SAME PAGE

In a survey of 756 adults with moderate-to-severe ulcerative colitis (UC), bowel urgency and fear of fecal incontinence were the top reasons they might miss out on activities of daily life. More than a third reported wearing diapers or other protection at least once a week because of this fear. Yet in a survey of 750 health care providers who care for patients with moderate-to-severe UC, bowel urgency and incontinence didn't even rank in the top three factors impacting treatment decisions. The survey findings suggest providers may not understand patients' chief concerns. Make sure your doctor has heard yours.

SOURCE: Inflammatory Bowel Diseases

Number of people with severe ulcerative colitis who will have to go to the hospital for their disease at some point.

SOURCE: American Family Physician

3.1 MILLION

Number of people in the U.S. who have IBD.

SOURCE: CDC

SENSE A FLARE BEFORE IT STARTS

The first symptoms of a Crohn's flare come after inflammation in your intestines has already begun to take its toll. Starting treatment when inflammation—rather than symptoms—begins could significantly reduce intestinal damage. But how can you tell it's started? Scientists have developed an implantable wireless sensor that can detect subtle temperature changes in the gut that indicate the start of inflammation. The device, which would be implanted in the GI tract, can transmit temperature data to a connected device and alert doctors to start treatment for a flare right away. The scientists are ready to begin testing the device in human intestinal tissue.

SOURCE: Nature Biomedical Engineering

WAS IT SOMETHING YOU ATE?

One in three people with Crohn's disease continue to have symptoms even when they no longer have active inflammation in their intestines. That's called quiescent disease. But what's causing those symptoms? It could be sulfur. When researchers analyzed stool samples of 39 people with guiescent Crohn's disease, they found high levels of sulfur. Sulfur-rich foods include meat, nuts, legumes, eggs, and cruciferous vegetables like broccoli, kale, and cauliflower. The study results suggest that a low-sulfur diet might help relieve lingering symptoms in quiescent Crohn's disease.

SOURCE: Inflammatory Bowel Diseases





Important Safety Information

- **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:
- 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).
- o **Infections.** 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.
- 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 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, pain in extremities, and with injections under the skin: pain, swelling, itching, hives, bruising, rash, or redness at the injection site. 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.
- Tell your healthcare provider about all the medicines you take, especially if you take or have recently taken Tysabri (natalizumab), Tyruko (natalizumab-sztn), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

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

ENTYVIO is available for:

- intravenous (IV) infusion: 300 mg vedolizumab.
- subcutaneous (SC) injection: 108 mg vedolizumab.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

What is ENTYVIO (vedolizumab)?

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

- moderately to severely active ulcerative colitis (UC).
- moderately to severely active Crohn's disease (CD).

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



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IMPORTANT FACTS

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

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

ENTYVIO® (en ti' vee oh) PEN (vedolizumab) injection, for subcutaneous use | subcutaneous 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
- 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
- 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 vou 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 (UC).
- moderately to severely active Crohn's disease (CD).

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 the 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 vour 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 FNTYVIO.
- are breastfeeding or plan to breastfeed. ENTYVIO can pass 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), Tyruko (natalizumab-sztn), a Tumor Necrosis Factor (TNF) blocker medicine, a medicine that weakens your immune system (immunosuppressant), or corticosteroid medicine.

How should I use ENTYVIO?

When given in a vein (intravenously):

- You may receive ENTYVIO through a needle placed in a vein (intravenous infusion) in your arm.
- ENTYVIO is given to you over a period of about 30
- 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.

When given under the skin (subcutaneously):

- You may receive ENTYVIO as an injection under your skin. (subcutaneous) every 2 weeks. You may receive your first subcutaneous injection after at least 2 intravenous infusions in place of the next scheduled intravenous infusion.
- See the detailed Instructions for Use that comes with ENTYVIO about the right way to prepare and give ENTYVIO.
- ENTYVIO is provided as single-dose prefilled syringe or single-dose prefilled pen (ENTYVIO PEN) for subcutaneous use. Your healthcare provider will prescribe the type that is best for you.
- If your healthcare provider decides that you or your caregiver can give your injections of ENTYVIO at home. you or your caregiver should be shown the right way to prepare and inject ENTYVIO.
- Do not inject ENTYVIO until you or your caregiver have been shown the right way by your healthcare provider.
- Always check the label of your prefilled syringe or prefilled pen to make sure you have the correct medicine before each injection.
- Do not shake ENTYVIO.
- ENTYVIO is injected under your skin (subcutaneously) 1 time every 2 weeks.

- Inject ENTYVIO under the skin (subcutaneous injection) in your upper legs (thighs) or stomach area (abdomen). The upper arms may also be used if a caregiver gives the injection.
- Use a different injection site each time you use ENTYVIO.
- Do not give an injection into moles, scars, bruises, or skin that is tender, hard, red, or damaged.
- If you are not able to inject ENTYVIO at your regular scheduled time or you miss a dose of ENTYVIO, inject the dose as soon as possible. Then, inject your next dose every 2 weeks thereafter. If you are not sure when to inject ENTYVIO, call your healthcare provider.
- If you take more ENTYVIO than you were told to take, call vour healthcare provider.

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, pain in extremities, and with injections under the skin: pain, swelling, itching, hives, bruising, rash, or redness at the injection site.

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. Do not use ENTYVIO for a condition for which it was not prescribed. Do not give ENTYVIO to other people, even if they have the same symptoms that vou have. It may harm them. 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-TAKEDA7 (1-877-825-3327).

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CHOOSING YOUR NEXT IBD TREATMENT

With moderate or severe IBD, the first treatments you try might not work. Here's how doctors decide what's next.

By Sonya Collins Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

f conventional treatments haven't relieved your symptoms or put your moderate-to-severe IBD in remission, it might be time to try something new.

"Patients should never just resign themselves to not feeling well," says Jami A. Kinnucan, MD, senior associate consultant at the Mayo Clinic in Jacksonville, FL. "If you still have active symptoms, you should discuss it with your care team."

If it's a different treatment you need, you've got options. That makes it more likely one of them will be just the right fit. But how do doctors choose?

SEVERITY OF INFLAMMATION

Now that you're moving on to the next treatment, your doctor will need to evaluate how inflamed your intestines still are. This may mean you need another colonoscopy.

"We want to know the severity of current inflammation because that's at least a partial factor in the decision about what therapy to use next," says Benjamin Cohen, MD, co-section head and clinical director for inflammatory bowel diseases at Cleveland Clinic in Ohio.

WHAT YOU'VE ALREADY TRIED

Some treatments work differently depending on what other medications you've already had in your system. Also, which treatments haven't worked for you in the past can give your doctor a better idea of what might work for you in the future.

SYMPTOMS OUTSIDE THE GUT

IBD is an intestinal disease, but some people also have inflammatory conditions outside the gut. "Many patients with IBD will have inflammatory arthritis, skin conditions, eye symptoms that are related to their inflammatory bowel disease," Cohen says. "Certain medications are going to be more effective at treating some of those simultaneous symptoms."

YOUR PLANS AND PREFERENCES

"Patient preference absolutely comes into play when we make decisions about treatment," Kinnucan says. For example, IBD medications can come in the form of pills, injections, and infusions. Some might work better with your lifestyle than others. Some medications are safe for people who are pregnant or trying to get pregnant, while others are not. Your doctor may ask you about these things.

YOUR HEALTH INSURANCE

No matter how well suited the medication is to your unique situation, it won't help you if it's out of your budget. "The elephant in the room is your insurance coverage," Cohen says. "At the end of the day, you have to be able to afford the medication you're on."

YOU HAVE OPTIONS

It may sound like a challenge to find a medication that would align with all of these unique factors, but that's now



more possible than ever before.

"Our current toolbox is exploding with many mechanisms and routes of administration for advanced IBD treatment," Kinnucan says. "The future is bright in terms of being able to offer patients options."

- deal breaker?
- + What activities are most important to get back to once my disease is under control?

OPTIONS FOR ULCERATIVE COLITIS

With a growing list of medicines, don't delay when you're ready for a switch

By Kendall K. Morgan Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

he goal of your ulcerative colitis (UC) treatment is to help you get your immune system and inflammation under control. While there's no cure, you'll have many advanced options to consider. There's no reason to settle for conventional therapies that aren't working well enough to control your symptoms and allow healing.

"Ten years ago, we had few types of medicines for ulcerative colitis, but over the past five years we've really had an explosion of options for patients, especially when UC is moderate to severe," says Elisa Boden, MD, a gastroenterologist specializing in inflammatory bowel disease (IBD) at Oregon Health & Science University in Portland, OR.

GROWING TREATMENT APPROACHES

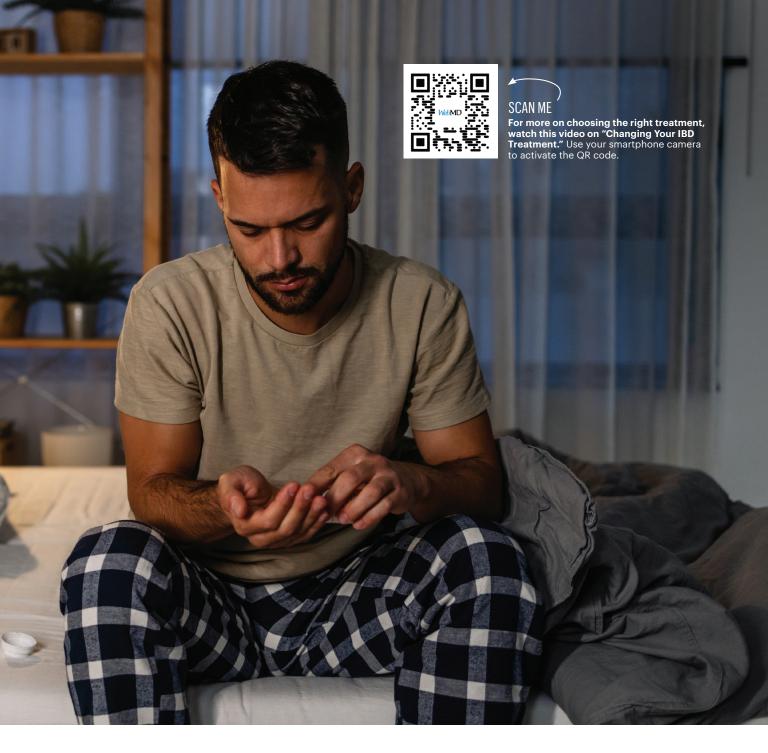
It's not just that the list of UC treatments is longer, but there are more options that work in different ways, says Edward L. Barnes, MD, MPH, a gastroenterologist and co-director of the UNC Multidisciplinary IBD Center at the University of North Carolina School of Medicine in Chapel Hill.

"We've seen rapid expansion in the treatment armamentarium for ulcerative colitis in terms of the sheer number of treatment options but also the different mechanisms of action," Barnes says. "From a patient perspective that's exciting because not so long ago, we only had one class of advanced therapies. Now we have so many mechanisms that if one [drug] class doesn't work, we have others we can pivot to. It's reassuring to know that if one medication doesn't work, it doesn't mean nothing is going to work."



EXPLORING OPTIONS

So-called conventional options for treating UC include aminosalicylates. They reduce inflammation when given in delayedrelease tablets or as enemas or suppositories. While these drugs may be used first, they're most likely to work when UC is milder. Corticosteroids may be used temporarily when your inflam-



mation is acute, but they don't work long-term, Boden says.

Today you'll have multiple choices of biologics, which are antibodies that can block certain proteins. Boden explains that anti-TNF biologics block a substance that drives inflammation while integrin receptor antagonists block immune cells' ability to cross from the blood into the intestine. One reason that's nice is that it doesn't have major effects on the body outside of the intestine, Boden says. Still another class of biologics block inflammatory substances called IL-23 or IL-12. New classes of oral medicines, including JAK inhibitors and S1P inhibitors, offer even more

choices, especially when other treatments haven't worked.

DON'T DELAY

Given all the options, Barnes says there's no reason to stick with conventional or other therapies for a long time if they're not working well.

"We should use the best evidence possible in a shared decision-making process to really improve quality of life," Barnes says. "If a patient is struggling, you need to reevaluate. We should be aggressive about that in the current era given all the treatment choices available."

MY **TREATMENT** PATH

From over-the-counter medications to biologics, I've tried it all

By Ashley Turner

Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

rohn's tried to beat me up over the years. But I haven't let it stop me from living my best life. I hope my journey encourages someone else along the way.

TESTS, TESTS, AND MORE TESTS

I battled digestive issues for more than 15 years—bad stomach cramps, blood in stool, constipation, nausea, and more. As a child, I even had canker sores a lot, which I now know is a symptom of IBD. My symptoms increased in my 20s while living away from home. I thought I was homesick. But when I returned home, my symptoms didn't go away. I saw a gastro doctor in Chicago and went through a series of tests, but no one could find out what was wrong.

My symptoms got so bad that I took a semester off from school to recover while working on my third degree. I was tested twice for Crohn's disease, and each time, I was told I didn't have it.

THINGS TURN AROUND

I finally graduated in 2017, but then my weight started dropping in 2021. And in 2022, I saw another gastro doctor in Atlanta. He did tests, and I remember him saying, "You have one of the worst cases of Crohn's I've ever seen." I bawled my eyes out, but it was a relief to finally have a diagnosis after so many years.

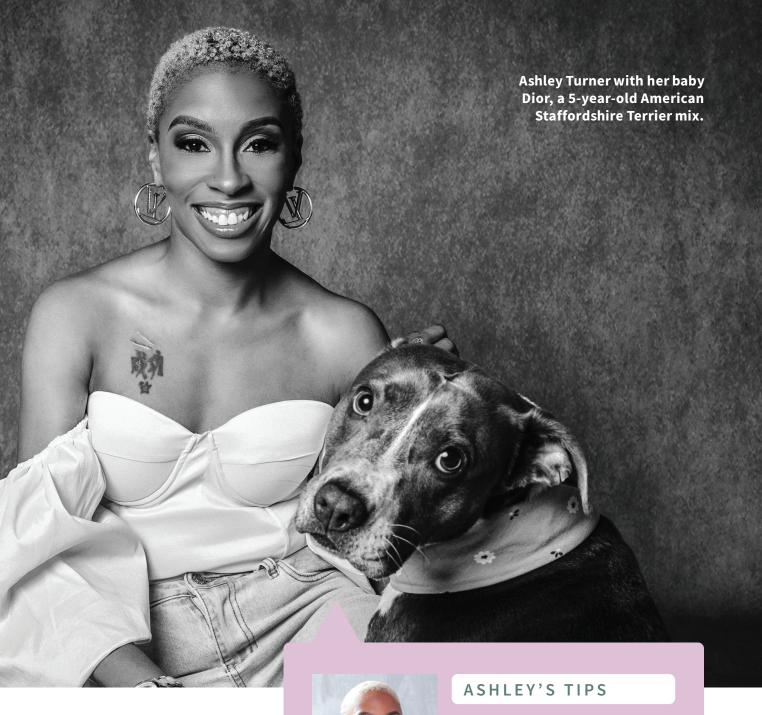
I'M STILL GONNA LIVE

I was on prednisone and other over-the-counter medications to help my Crohn's



symptoms. Oral medications never worked well for me, so today I'm on biologics that work great. I also watch what I eat. I limit dairy and citrus food and don't eat beef or pork. I also work out regularly with a trainer.

Although I'm not a mom to humans, I'm a mom to a 5-year-old pup named Dior. She, too, has Crohn's. I'm glad I'm her fur mom because I know what to look for. We have the same story-in and out of doctors' offices for me, in and out



of veterinary clinics for her. I'm on injections for my Crohn's, which help. She's on pills and is doing well.

Crohn's might slow me down, but it doesn't stop me. I know my case is more severe. I share this message as an advocate for COGI (Color of Gastrointestinal Illnesses) and on my IG page (@theemichaelashley).

I've written one self-help journal (Gut Feelings: A Journal for Those with Gastrointestinal Illnesses) and I have two more that are scheduled to

- + **Be vigilant.** Ask the crazy questions of your doctors.
- + Be organized. Record your doctor visits (with permission).
- + Be active. Working out has been my saving grace.

be released later this year. I cultivate my passion for food, fashion, music, and global travel. I'm in the IT industry, so I call myself the "IT" girl! For me, that means using my voice to ensure other people who look like me—who often go unseen-have a voice.

MANAGE THE COSTS OF YOUR IBD TREATMENT

Know where to find help with medications and protect yourself from added costs down the road

By Kendall K. Morgan Reviewed by Neha Pathak, MD, WebMD Lead Medical Editor

hen you have inflammatory bowel disease (IBD), the costs may feel daunting. Uncontrolled IBD and its symptoms also come with many indirect costs as you may struggle to continue in school, go to work, and enjoy life as you should. The sooner you can get your IBD controlled, the more likely it is you'll avoid more costly complications later, says Jason Ken Hou, MD, a gastroenterologist at Baylor College of Medicine in Houston, TX.

"The data has shown that being on the right medication reduced the cost of these other problems, which has a whole other impact on life," Hou says. "If a patient is poorly controlled and requires repeated bowel surgery, that can have a really dramatic impact on their quality of life and

other conditions or complications that may still need medications long-term."

KNOW YOUR INSURANCE PLAN

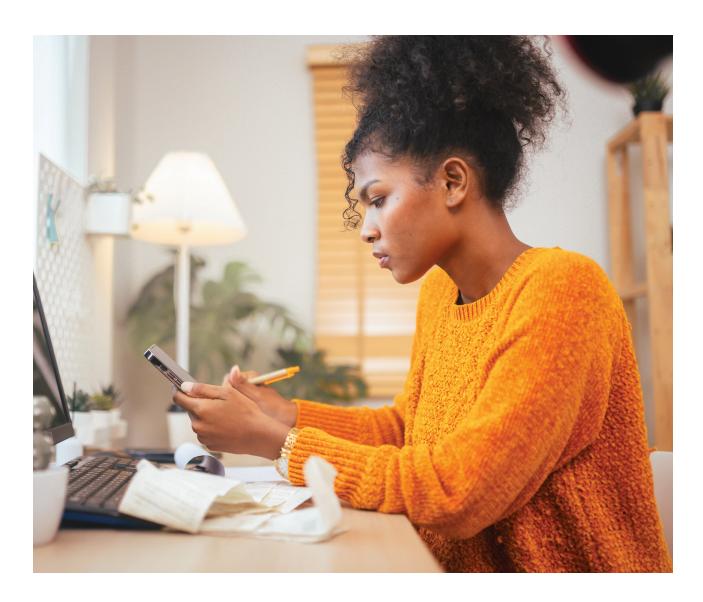
You'll have many advanced treatment options, including biologics, that can make a big difference in how you feel. To manage your out-of-pocket costs, it's important to understand your insurance plan and make sure you've got the coverage you need.

"I encourage patients to look at the type of pharmacy coverage they have and, in general, to avoid or be cautious of plans that require them to be responsible for a proportion of medication costs as opposed to flat fees," Hou says.

WHERE TO FIND HELP

For more information and resources about managing IBD costs, see:

- + Managing the Cost of IBD https://www.crohnscolitisfoundation.org/patientsandcaregivers/managing-the-cost-of-ibd
- + Crohn's & Colitis Foundation's IBD Help Center https://www.crohnscolitisfoundation.org/patientsandcaregivers/community-support/the-ibd-help-center
- + How to Get Help with Medical Bills



UNDERSTANDING APPEALS

Studies have shown that people with IBD often struggle to access prescribed medicines or experience treatment delays awaiting insurance approvals. You may feel powerless if your insurance company initially refuses to pay for your medication, but there are steps you can take.

"Patients should know there are options to appeal those decisions," says Laura D. Wingate, chief education, support, and advocacy officer at the Crohn's & Colitis Foundation in New York City.

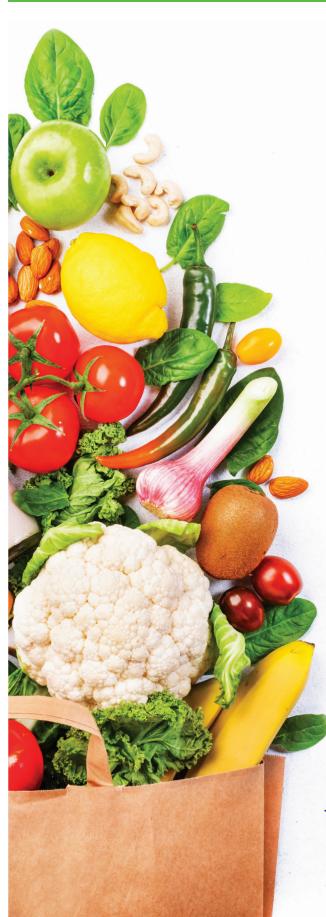
Wingate recommends asking your doctor for assistance, as they will have experience and avenues to help you navigate your insurance. If your insurance is through an employer, let your benefits team know about the delays and ask if they can assist. The Crohn's & Colitis Foundation's

IBD Help Center also is staffed with experts ready to assist you, Wingate says.

TACKLE FINANCIAL STRESS

It's important to recognize that stress related to your finances and insurance coverage can take a serious toll on you mentally, Wingate says. Mental health concerns including anxiety and depression are also an important driver of added IBD costs. In addition to the cost concerns, she recommends reaching out to national or local organizations as a source of emotional support, too.

"It can help to talk to another person with IBD that has gone through appealing insurance decisions," Wingate says. "Get the emotional support you might need and that sense of community that you're not alone."





Gut Friendly RECIPES

A World of Food for IBD Patients

Knowing what to eat can be tricky if you have inflammatory bowel disease (IBD). Our Gut Friendly Recipes—powered by Nestlé Health Science—helps take the stress out of making meal choices and allows you to enjoy cooking! With one click of this digital tool, you can explore a world of food that's right for your dietary needs and personal tastes.

All recipes have been approved by dietitians that specialize in IBD, and this new resource is free to use.

Get the nutrition you need while eating foods that taste great!

At Gut Friendly Recipes, users can:

- **Filter hundreds of recipes** by meal type, exclusions and more!
- Find recipes for the Crohn's Disease Exclusion Diet, Mediterranean Diet, Low FODMAP diet, and Specific Carbohydrate Diet™
- Choose foods they want to exclude
- Access special features through free registration: save favorite recipes, create seven-day meal plans, and more!

Get cooking with Gut Friendly Recipes today at gutfriendlyrecipes.org

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