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GI & Hepatology News

American Gastroenterological Association's official newspaper
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Satish S.C. Rao
MD, PhD

Noninvasive neuromodulation reduces fecal incontinence in phase 3 trial

Six weeks of transumbrosacral magnetic stimulation cut fecal incontinence episodes by at least half in up to 81% of patients and improved measures of nerve and sphincter function.

By Doug Brunk

Transumbrosacral neuromodulation therapy (TNT) cut weekly fecal incontinence episodes by at least half in 66% to 81% of patients after six weeks, compared with 32% of those

receiving sham treatment.

The phase 3, multicenter, double-blind, sham-controlled trial evaluated TNT, a noninvasive treatment that delivers repetitive magnetic stimulation to the lumbar and sacral plexus nerves that regulate anorectal function. The study, published in

Gastroenterology, was conducted at two US academic centers from 2019 through 2024.

"There are very few treatment options for fecal incontinence, a devastating problem that plagues the lives of millions of Americans and affects over 9% of the population,"

Six-trial analysis finds no new upadacitinib safety signals in IBD

No new safety signals were found with long-term upadacitinib treatment for UC and Crohn's. Blood clots, major cardiovascular events, and cancers remained uncommon, while shingles increased with dose. The findings offer reassurance, though longer-term real-world data are still needed to assess uncommon risks.

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first author Satish S.C. Rao, MD, PhD, the Harold Harrison Distinguished University Chair in Gastroenterology at Augusta University, Augusta, Georgia, told *GI & Hepatology News*. "Of those available, there is limited scientific evidence that they work or are proven in large scientific trials. Here we have not only demonstrated significant clinical improvement using the best and universally accepted responder definition (a 50% reduction in fecal incontinence episodes) but concurrently have demonstrated improvement in fecal incontinence severity and quality of life."

[Continues • Page 11](#)

UnitedHealthcare to end GI endoscopy advance notification, site-of-service reviews

"Anytime an insurer says we're going to lessen the administrative burden on our members, it's a welcome sign," said Kathleen Teixeira, AGA's vice president of practice and advocacy. "We know that prior authorization is a tremendous burden on our physicians and their practices."

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** Infusion-related reactions and hypersensitivity reactions, including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate, have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- **Infections:** ENTYVIO increases the risk for developing infections. Serious infections in clinical trials included anal abscess, sepsis (some fatal), tuberculosis (TB), salmonella sepsis, *Listeria* meningitis, giardiasis, and cytomegaloviral colitis. Postmarketing reports include systemic bacterial, fungal, viral, and parasitic opportunistic infections. Do not start ENTYVIO in patients with a clinically important active infection until resolved or adequately treated. In patients with chronic infection or history of recurrent infection, consider risks and benefits prior to ENTYVIO. Instruct patients to seek medical advice if signs or symptoms of acute or chronic infection occur. If a serious infection develops or does not respond to therapy, monitor closely and do not administer ENTYVIO until resolved.

Tuberculosis: Consider evaluating for TB prior to ENTYVIO. Do not administer ENTYVIO to patients with active TB. Before starting ENTYVIO, treat latent TB and consider anti-TB therapy in patients with a history of TB if adequate course of treatment cannot be confirmed. Monitor for active TB during and after ENTYVIO.

- **Progressive Multifocal Leukoencephalopathy (PML):** PML, a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- **Liver Injury:** There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- **Immunizations:** Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

For adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease.



THE ONLY GUT-FOCUSED BIOLOGIC* FOR CROHN'S AND UC

**When your patients want options...
maintain treatment their way with
the ENTYVIO Pen at home or on the go^{1†}**

***ENTYVIO specifically binds to the $\alpha 4\beta 7$ integrin and blocks its interaction with MAdCAM-1, which is mainly expressed on gut endothelial cells.¹**

†The ENTYVIO Pen is a maintenance option after at least 2 IV infusions.¹

**‡ENTYVIO must be refrigerated and protected from light.
It can be kept at room temperature for 7 days; do not freeze.**

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 3\%$ and $\geq 1\%$ higher than placebo) were: nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, pain in extremities, and injection site reactions with subcutaneous administration.

DRUG INTERACTIONS

Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products and with TNF blockers. Upon initiation or discontinuation of ENTYVIO in patients treated with CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP substrate as needed.

INDICATIONS

ENTYVIO is indicated in adults for the treatment of:

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

DOSAGE FORMS & STRENGTHS

- ENTYVIO Intravenous Infusion: 300 mg vedolizumab;
Subcutaneous Injection: 108 mg vedolizumab

Please see accompanying Brief Summary of Full Prescribing Information on adjacent pages.

IV=intravenous; MAdCAM-1=mucosal addressin cell adhesion molecule-1.

Reference: 1. ENTYVIO (vedolizumab) prescribing information. Takeda Pharmaceuticals.



**Visit ENTYVIOHCP.com
to see dosing,
administration, and
storage details.**

If you are a Colorado prescriber, please see the Colorado WAC disclosure form at [Takeda.info/ENTYVIOHCPricing](https://www.takeda.com/ENTYVIOHCPricing).

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

Consult the Full Prescribing Information for complete product information.

ENTYVIO (vedolizumab) for injection, for intravenous use
ENTYVIO (vedolizumab) injection, for subcutaneous use
ENTYVIO PEN (vedolizumab) injection, for subcutaneous use

INDICATIONS AND USAGE

ENTYVIO is indicated in adults for the treatment of:

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

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients (such as dyspnea, bronchospasm, urticaria, flushing, rash and increased heart rate) [see Warnings and Precautions].

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions and Hypersensitivity Reactions

Infusion-related reactions and hypersensitivity reactions have been reported, including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate [see Adverse Reactions]. These reactions may occur with the first or subsequent infusions of ENTYVIO and may vary in their time of onset from during infusion or up to several hours post-infusion.

If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Infections

Patients treated with ENTYVIO are at increased risk for developing infections [see Adverse Reactions]. Serious infections reported in clinical trials include anal abscess, sepsis (some fatal), tuberculosis (TB), salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. Postmarketing cases of systemic bacterial, fungal, viral, and parasitic opportunistic infections have been reported.

Treatment with ENTYVIO should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ENTYVIO. During treatment with ENTYVIO, instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely. ENTYVIO should not be administered until the infection resolves.

Tuberculosis

Consider evaluating patients for TB infection prior to initiating treatment with ENTYVIO. Treatment with Entyvio should not be administered to patients with active TB infection. Initiate treatment of latent TB prior to administering ENTYVIO. Consider anti-TB therapy prior to initiation of ENTYVIO in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after ENTYVIO treatment.

Progressive Multifocal Leukoencephalopathy

PML, a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported in the postmarketing setting (e.g., human immunodeficiency virus [HIV] infection with a CD4 count of 300 cells/mm³ and prior and concomitant immunosuppression). Although unlikely, a risk of PML cannot be ruled out.

Monitor patients on ENTYVIO for any new onset, or worsening, of neurological signs and symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. The progression of deficits usually leads to death or severe disability over weeks or months. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue dosing permanently.

Liver Injury

There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. In general, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury [see Adverse Reactions].

Immunizations

Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines (e.g., influenza vaccine injection) and may receive live vaccines if the benefits outweigh the risks. There are no data on the secondary transmission of infection by live vaccines in patients receiving ENTYVIO [see Adverse Reactions].

ADVERSE REACTIONS

The following topics are also discussed in detail in the Warnings and Precautions section:

- Infusion-Related Reactions and Hypersensitivity Reactions [see Warnings and Precautions]
- Infections [see Warnings and Precautions]
- Progressive Multifocal Leukoencephalopathy [see Warnings and Precautions]
- Liver Injury [see Warnings and Precautions]

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 data described below reflect exposure to intravenous ENTYVIO in 3,326 patients and healthy volunteers in clinical trials, including 1,396 exposed for greater than one year, and 835 exposed for greater than two years.

Intravenous Infusion

The safety data described in Table 1 are derived from four controlled Phase 3 trials (UC Trials I and II, and CD Trials I and III); data from adult patients receiving open-label intravenous ENTYVIO treatment at Weeks 0 and 2 (prior to entry into UC Trial II and CD Trial III) and from Weeks 6 to 52 (non-responders at Week 6 of UC Trial I and CD Trial I) are included.

In these trials, 1,434 patients received ENTYVIO 300 mg intravenously for up to 52 weeks, and 297 patients received placebo for up to 52 weeks. Of these, 769 patients had ulcerative colitis and 962 patients had Crohn’s disease. Patients were exposed for a mean duration of 259 days (UC Trials I and II) and 247 days (CD Trials I and III).

Adverse reactions were reported in 52% of patients treated with intravenous ENTYVIO and 45% of patients treated with placebo (UC Trials I and II: 49% with ENTYVIO and 37% with placebo; CD Trials I and III: 55% with ENTYVIO and 47% with placebo). Serious adverse reactions were reported in 7% of patients treated with intravenous ENTYVIO compared to 4% of patients treated with placebo (UC Trials I and II: 8% with ENTYVIO and 7% with placebo; CD Trials I and III: 12% with ENTYVIO and 9% with placebo).

The most common adverse reactions (reported by ≥3% of patients treated with intravenous ENTYVIO in the UC Trials I and II and CD Trials I and III combined group and ≥1% higher than in combined placebo group) were nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain and pain in extremities (Table 1).

Table 1. Adverse Reactions in ≥3% of Intravenous ENTYVIO-Treated Adult Patients and ≥1% Higher than in Placebo (UC Trials I and II* and CD Trials I and III*)

Adverse Reaction	ENTYVIO IV† (N=1434)	Placebo‡ (N=297)
Nasopharyngitis	13%	7%
Headache	12%	11%
Arthralgia	12%	10%
Nausea	9%	8%
Pyrexia	9%	7%
Upper respiratory tract infection	7%	6%
Fatigue	6%	3%
Cough	5%	3%
Bronchitis	4%	3%
Influenza	4%	2%
Back pain	4%	3%
Rash	3%	2%
Pruritus	3%	1%
Sinusitis	3%	1%
Oropharyngeal pain	3%	1%
Pain in extremities	3%	1%

* Data from patients receiving open-label intravenous ENTYVIO treatment at Weeks 0 and 2 (prior to entry into UC Trial II and CD Trial III) and from Weeks 6 to 52 (non-responders at Week 6 of UC Trial I and CD Trial I) are included.

† Patients who received ENTYVIO for up to 52 weeks.

‡ Patients who received placebo for up to 52 weeks.

Safety data for patients (n=279) in UC Trials I and II and CD Trials I and III who received intravenous ENTYVIO at Weeks 0 and 2 and were then randomized to placebo at Week 6 for up to 52 weeks, and for patients (n=416) in CD Trial II, a 10-week Crohn’s disease trial, are similar to those listed in Table 1.

Infusion-Related Reactions and Hypersensitivity Reactions

Serious infusion-related reactions and hypersensitivity reactions including anaphylaxis have been reported following intravenous ENTYVIO administration in clinical trials [see Warnings and Precautions]. In UC Trials I and II and CD Trials I and III, one case of anaphylaxis [one out of 1,434 patients treated with intravenous ENTYVIO (0.07%)] was reported by a Crohn’s disease patient during the second infusion (symptoms reported were dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate) and was managed with discontinuation of infusion and treatment with antihistamine and intravenous hydrocortisone.

In UC Trials I and II and CD Trials I and III, 4% of patients treated with intravenous ENTYVIO and 3% of patients treated with placebo experienced an infusion-related reaction (IRR). The most frequently observed IRRs in the patients treated with intravenous ENTYVIO (reported more than twice) were nausea, headache, pruritus, dizziness, fatigue, infusion-related reaction, pyrexia, urticaria, and vomiting (each of these adverse reactions occurred in <1% in all patients treated with intravenous ENTYVIO) and no individual adverse reaction reported occurred at a rate above 1%. These reactions generally occurred within the first two hours after the infusion and resolved with no treatment or following antihistamine and/or IV hydrocortisone treatment. Less than 1% of patients treated with intravenous ENTYVIO had IRRs assessed by the investigator as severe, and IRRs requiring discontinuation of study treatment occurred in <1%.

In clinical trials, for patients with mild IRRs or hypersensitivity reactions, physicians were allowed to pretreat with standard medical treatment (e.g., antihistamine, hydrocortisone, and/or acetaminophen) prior to next infusion.

Infections

In UC Trials I and II and CD Trials I and III, the rate of infections was 0.85 per patient-year in the patients treated with intravenous ENTYVIO and 0.7 per patient-year in the patients treated with placebo [see Warnings and Precautions]. The infections consisted primarily of nasopharyngitis, upper respiratory tract infection, sinusitis, and urinary tract infection. Two percent of patients discontinued intravenous ENTYVIO due to infections.

In UC Trials I and II and CD Trials I and III, the rate of serious infections was 0.07 per patient-year in patients treated with intravenous ENTYVIO and 0.06 per patient-year in patients treated with

placebo. Serious infections were more common in Crohn's disease patients than ulcerative colitis patients, and anal abscesses were the most frequently reported serious adverse reaction in Crohn's disease patients. Over 48 months, there was no increase in the rate of serious infections.

In controlled- and open-label long-term extension trials in adults treated with intravenous ENTYVIO, serious infections have been reported, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis.

In UC Trials I and II and CD Trials I and III, sepsis, including bacterial sepsis and septic shock, was reported in four of 1,434 (0.3%) patients treated with intravenous ENTYVIO and in two of 297 patients treated with placebo (0.7%). During these trials, two Crohn's disease patients treated with intravenous ENTYVIO died due to reported sepsis or septic shock; both patients had significant comorbidities and a complicated hospital course that contributed to the deaths. In an open label, long-term extension trial, additional cases of sepsis (some fatal), including bacterial sepsis and septic shock, were reported. The rate of sepsis in patients with ulcerative colitis or Crohn's disease receiving intravenous ENTYVIO was two per 1,000 patient-years.

In clinical trials, all patients were screened for tuberculosis. One case of latent, pulmonary tuberculosis was diagnosed during the controlled trials with intravenous ENTYVIO. Additional cases of pulmonary tuberculosis were diagnosed during the open-label trial. All of these observed cases occurred outside the United States (U.S.), and none of the patients had extrapulmonary manifestations.

Liver Injury

There have been reports of elevations of transaminase and/or bilirubin in patients receiving intravenous ENTYVIO [*see Warnings and Precautions*]. In UC Trials I and II and CD Trials I and III, three patients reported serious adverse reactions of hepatitis, manifested as elevated transaminases with or without elevated bilirubin and symptoms consistent with hepatitis (e.g., malaise, nausea, vomiting, abdominal pain, anorexia). These adverse reactions occurred following two to five intravenous ENTYVIO doses; however, based on case report information it is unclear if the reactions indicated drug-induced or autoimmune etiology. All patients recovered following discontinuation of therapy with some requiring corticosteroid treatment. In controlled trials, the incidence of ALT and AST elevations ≥3x ULN was <2% in patients treated with intravenous ENTYVIO and in patients treated with placebo. In the open-label trial, one additional case of serious hepatitis was observed.

Malignancies

In UC Trials I and II and CD Trials I and III, malignancies (excluding dysplasia and basal cell carcinoma) were reported in six of 1,434 (0.4%) patients treated with intravenous ENTYVIO, including colon cancer (n=2), transitional cell carcinoma (n=1), breast cancer (n=1), carcinoid tumor of the appendix (n=1) and squamous cell carcinoma (n=1). Malignancy was reported in one of 297 (0.3%) patients treated with placebo (squamous cell carcinoma).

Malignancies (excluding dysplasia and basal cell carcinoma) observed during the ongoing open-label long-term extension trial included B-cell lymphoma, breast cancer, colon cancer, malignant hepatic neoplasm, malignant lung neoplasm, malignant melanoma, lung cancer of primary neuroendocrine carcinoma, renal cancer and squamous cell carcinoma. Overall, the number of malignancies in the clinical trials was small; however, long-term exposure was limited.

Subcutaneous Injection after Two Intravenous Doses of ENTYVIO

ENTYVIO was administered as a subcutaneous injection in adult patients with ulcerative colitis and Crohn's disease in double-blind, placebo-controlled clinical trials (SC UC Trial and SC CD Trial, respectively). Patients who achieved clinical response following two doses of ENTYVIO administered as an intravenous infusion at Week 0 and Week 2 were randomized 2:1 at Week 6 to ENTYVIO as a subcutaneous injection (N=106) or placebo (N=56) (SC UC Trial) and as subcutaneous injection (N=275) or placebo (N=134) (SC CD Trial).

The safety profile for up 52 weeks of total treatment was similar between patients who were switched to ENTYVIO as a subcutaneous injection in SC UC and SC CD clinical trials and patients in UC and CD clinical trials who received ENTYVIO as an intravenous infusion (*Table 1*) except for injection site reactions, which were reported with subcutaneous ENTYVIO. Injection site reactions with subcutaneous ENTYVIO were reported in 10% (11/106) of patients in SC UC Trial, including injection site erythema, rash, pruritus, swelling, bruising, and hematoma. Injection site reactions with subcutaneous ENTYVIO were reported in 3% (8/275) of patients in SC CD Trial, including injection site erythema, pruritus, urticaria, pain, rash, and edema.

Live and Oral Vaccines

There are no data on the secondary transmission of infection by live vaccines in patients receiving ENTYVIO.

In a placebo-controlled study of healthy volunteers, 61 subjects were given a single intravenous ENTYVIO 750 mg dose (2.5 times the recommended dose), and 62 subjects received placebo followed by intramuscular vaccination with Hepatitis B surface antigen and oral cholera vaccine. After intramuscular vaccination with three doses of recombinant Hepatitis B surface antigen, those treated with intravenous ENTYVIO did not have lower rates of protective immunity to Hepatitis B virus. However, those exposed to intravenous ENTYVIO did have lower seroconversion rates and anti-cholera titers relative to placebo after receiving the two doses of a killed, oral cholera vaccine. The impact on other oral vaccines and on nasal vaccines in patients is unknown.

Postmarketing Experience

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

Immune system disorders: Anaphylaxis [*see Warnings and Precautions*]

Gastrointestinal system disorders: Acute Pancreatitis

Respiratory, thoracic, and mediastinal disorders: Interstitial lung disease, pneumonitis.

DRUG INTERACTIONS

Natalizumab Products

Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products.

TNF Blockers

Because of the potential for increased risk of infections, avoid the concomitant use of ENTYVIO with TNF blockers.

CYP450 Substrates

The formation of CYP450 enzymes may be suppressed by increased levels of certain cytokines (e.g., IL-6, IL-10, TNFα, IFN) during chronic inflammation. Therefore, use of ENTYVIO may normalize the formation of CYP450 enzymes by modulating the underlying disease. Upon initiation or discontinuation of ENTYVIO in patients treated with CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP substrate as needed. See the prescribing information of specific CYP substrates.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available data from the Organization of Teratology Information Specialists (OTIS)/MotherToBaby ENTYVIO Pregnancy Registry, published literature and pharmacovigilance in pregnant women have not reliably identified an ENTYVIO-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes (*see Data*). There are risks to the mother and the fetus associated with inflammatory bowel disease in pregnancy (*see Clinical Considerations*).

No fetal harm was observed in animal reproduction studies with intravenous administration of vedolizumab to rabbits and monkeys at dose levels 20 times the recommended human dosage (*see Data*).

The background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and miscarriage is 15 to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and Embryo/Fetal Risk

Published data suggest that the risk of adverse pregnancy outcomes in women with inflammatory bowel disease (IBD) is associated with increased disease activity. Adverse pregnancy outcomes include preterm delivery (before 37 weeks of gestation), low birth weight (less than 2,500 g) infants, and small for gestational age at birth.

Fetal/Neonatal Adverse Reactions

ENTYVIO administered during pregnancy could affect immune responses in the in utero-exposed newborn and infant. The clinical significance of low levels of ENTYVIO in utero-exposed infants is unknown. The safety of administering live or live-attenuated vaccines in exposed infants is unknown.

Data

Human Data

The vedolizumab pregnancy exposure registry conducted by OTIS/MotherToBaby study in the United States and Canada collected prospective observational data between 2015 and 2022 to assess the risk of major birth defects in live-born infants of women with ulcerative colitis (UC) or Crohn's disease (CD) treated with vedolizumab during pregnancy. The study compared pregnant patients with UC or CD exposed to vedolizumab with pregnant patients with UC or CD treated with other biological products. The registry included 99 women (58 with UC, 41 with CD) treated with vedolizumab during pregnancy, and 76 women (27 with UC, 49 with CD) exposed to other biological products during pregnancy.

The proportion of major birth defects among live-born infants in patients with UC or CD treated with vedolizumab and patients with UC or CD treated with other biological products was 7.4% (7/94) and 5.6% (4/71), respectively. Overall, there was no evidence of increased risk for major structural birth defects (adjusted RR 1.07, 95% CI: 0.33, 3.52).

The methodological limitations of the registry, including small sample size and the non-randomized design, resulted in a limited ability to estimate the risk of major birth defects and other maternal and infant outcomes. The conclusions from the pregnancy registry were consistent with the published literature and pharmacovigilance.

Animal Data

A reproduction study has been performed in pregnant rabbits at single intravenous doses up to 100 mg/kg administered on gestation Day 7 (about 20 times the recommended human dosage) and has revealed no evidence of impaired fertility or harm to the fetus due to vedolizumab. A pre- and post-natal development study in monkeys showed no evidence of any adverse effect on pre- and post-natal development at intravenous doses up to 100 mg/kg (about 20 times the recommended human dosage).

Lactation

Risk Summary

Data from a clinical lactation study show the presence of vedolizumab in human milk. The mean calculated daily infant dosage was 0.02 mg/kg/day orally (*see Data*). Systemic exposure in a breastfed infant is expected to be low because monoclonal antibodies are largely degraded in the gastrointestinal tract. There are no data on the effects of vedolizumab on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ENTYVIO and any potential adverse effects on the breastfed infant from ENTYVIO or from the underlying maternal condition.

Data

A milk-only lactation study was conducted in 9 adult lactating women being treated for active ulcerative colitis or Crohn's disease with intravenous ENTYVIO every 8 weeks after reaching steady state and completing the induction phase (ENTYVIO administration at 0, 2, and 6 weeks). Mean concentrations of ENTYVIO in human milk ranged from 0.03 to 0.26 mcg/mL. The mean calculated daily infant oral dosage was 0.02 mg/kg/day calculated as a product of the average concentration over the 8-week dosing interval and the standardized milk consumption of 150 mL/kg/day.

Pediatric Use

Safety and effectiveness of ENTYVIO in pediatric patients have not been established.

Geriatric Use

Clinical trials of ENTYVIO did not include sufficient numbers of patients aged 65 and over (72 patients with Crohn's or ulcerative colitis patients aged 65 and over were treated with ENTYVIO during controlled Phase 3 trials) to determine whether they respond differently from younger adult patients. However, no overall differences in safety or effectiveness were observed between these patients and younger adult patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Manufactured by:

Takeda Pharmaceuticals U.S.A., Inc.

Cambridge, MA 02142

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Revised: February 2026

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For more information, go to www.ENTYVIO.com or call 1-877-TAKEDA7 (1-877-825-3327).

US-VED-4326 03/26

A new chapter for GI & Hepatology News

As a new editorial board takes the helm, we remain focused on delivering timely, practice-changing news while listening to the readers we serve.



This October 2026 issue marks the transition to a new editorial board for *GI & Hepatology News*. I am deeply humbled and grateful for the opportunity to serve as the next editor in chief. I follow Megan Adams, MD, JD, MSc, who steadfastly led the newspaper through remarkable growth over the past 5 years, as well as through the transition to a new publisher (Conexiant) earlier this year. She leaves an exemplary legacy and is a tough act to follow.

Joining me is an accomplished and dedicated group of associate editors representing a broad range of practice environments, geographic regions, and specialty interests within gastroenterology and hepatology. They have been selected with the diverse interests and backgrounds of our readers in mind. Close collaboration among the editorial board, publisher, and AGA staff will help ensure a smooth transition while maintaining the high level of quality and relevance you expect from *GI & Hepatology News*.

An invaluable source of feedback for our continued growth and improvement is you, our readers. We welcome your comments, suggestions, and opinions. Although we cannot guarantee that every suggestion will be implemented, we can promise that all feedback will be carefully considered. We want to continue improving for you and with you.

This issue features several practice-changing developments stemming from large, double-blind randomized controlled trials. We highlight an encouraging phase 3 trial showing that noninvasive translumbar sacral neuromodulation reduced fecal incontinence in 109 adults whose symptoms were refractory to conventional treatments. We report on the FDA approvals of a second blood-based colorectal cancer screening test and an expanded indication for ustekinumab (Stelara) in pediatric ulcerative colitis. We also present a large randomized controlled trial involving 1,879 adults with Lynch syndrome, which found that 100 mg/day of aspirin was sufficient to reduce cancer risk, making the previously studied high dose of 600 mg/day unnecessary. These are but a few examples of how clinical research continues to drive progress in patient care.

This is an exciting time in gastroenterology. Rapid advances in research are producing breakthroughs in treatments, improvements in care delivery, and renewed hope for our patients. In this dynamic era, we look forward to serving as your trusted, go-to news source in gastroenterology and hepatology.

Berkeley N. Limketkai, MD, PhD
Editor in Chief

Call for nominations

Know an inspiring AGA member? Nominate them to be featured in a Member Spotlight.

Do you know an AGA member with a unique, inspiring, or particularly interesting career path? Nominate them for our Member Spotlight! We would love to share their story with the AGA community. Our members are doing remarkable work in clinical care, research, education, advocacy, and innovation, and highlighting these journeys helps celebrate the diverse experiences that shape the field of gastroenterology.

To submit a nomination or suggestion, please email the member's name and a brief note about why they would be a great feature to ginews@gastro.org. We look forward to hearing about the inspiring members in your network!



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The New Gastroenterologist • See page 20



UnitedHealthcare to end GI endoscopy advance notification, site-of-service reviews

The Oct. 1 changes reverse the notification policy born from the 2023 prior-authorization fight and end hospital-outpatient reviews, including for screening colonoscopy. AGA says the decision shows its payor engagement is paying off.

By [Bob Alaburda](#)

UnitedHealthcare (UHC) will stop requesting advance notification for select GI endoscopy procedures and end all GI site-of-service reviews — including for screening colonoscopy — for UHC commercial plan members and Oxford plan members in New York and Connecticut beginning Oct. 1, 2026.

The advance-notification change covers esophagogastroduodenoscopy, capsule endoscopy, and diagnostic and surveillance colonoscopy. Screening colonoscopies were not subject to advance notification, but they and a subset of the other endoscopy services required site-of-service medical-necessity review when planned in a hospital outpatient setting. For procedures performed on or after Oct. 1, those reviews will end as well. UHC said in a Sept. 1 provider notice the changes are intended to “simplify access to care and reduce complexity.” They arrived alongside a broader Sept. 1 disclosure of roughly 1,700 codes coming off prior authorization across UHC plans, fulfilling the insurer’s May commitment to cut 30% of its remaining prior authorization volume by the end of 2026.

For AGA, the changes close out the advance-notification process UHC adopted after withdrawing its contested 2023 prior authorization proposal and go further by eliminating GI site-of-service reviews that predated that fight.

An earlier round of UHC prior authorization reductions had included little for gastroenterology, said Leslie Narramore, AGA’s senior director of regulatory affairs, so AGA was initially cautious. Its review of the newly published commercial code list changed that. “They managed to grab all of the codes that represent the high-volume services that GIs do,” she said. “It’s a significant win for those who have a high market share of United.”

AGA’s review found that the commercial list captures the high-volume EGD, colonoscopy, capsule endoscopy, and screening-colonoscopy codes most relevant to GI practices. The GI-specific announcement does not encompass every endoscopic procedure; ERCP and

certain small-bowel endoscopy services fall outside the categories it names, Narramore said. AGA is reviewing whether any separate plan-specific requirements apply to those services.

“Anytime an insurer says we’re going to lessen the administrative burden on our members, it’s a welcome sign,” said Kathleen Teixeira, AGA’s vice president of practice and advocacy. “We know that prior authorization is a tremendous burden on our physicians and their practices.”

What changes for GI practices

Beginning Oct. 1, UHC will no longer request advance notification for the listed procedures for affected commercial and Oxford members, and site-of-service review will end for procedures performed on or after that date.

AGA cautioned that the change does not eliminate every preprocedural step. Practices may still choose to seek predetermination for payment certainty and liability reasons, Narramore said, so some burden will remain. “But I do think it will result in a meaningful reduction, because you don’t have to go through that second step” to feel confident a procedure will be paid, she said.

Some operational details remain unresolved. UHC’s public notice confirms that site-of-service review will end for affected procedures performed on or after Oct. 1, but it does not explain how pending requests will be handled, whether portal prompts will stop automatically, or whether practices need to change any internal workflows. AGA expects additional logistical guidance in the coming weeks. UHC continues to direct practices to verify member-specific requirements through its Prior Authorization and Notification tool because plan-specific exceptions may apply.

AGA documented member reports of substantial administrative burden soon after the program began. In an August 2023 letter to UHC, AGA said large practices reported spending five to seven minutes per patient on notification entries, estimated workload increases of 25% to 35%, and in some cases dedicated



full-time employees to UHC accounts.

Teixeira said the change removes one layer of a broader utilization-management burden that consumes substantial staff and physician time. “Practices, depending on the size, have full-time employees — this is all they do,” Teixeira said. “It frees up time for the office staff and for the physician, who a lot of times needs to get on the phone and do a peer-to-peer. Hopefully it will speed up the time to care for patients.”

The payor partnership

AGA views the announcement as the most visible result of a deliberate expansion of its advocacy strategy. After the 2023 campaign, the association launched its Payor Partnership — chaired by Lawrence Kosinski, MD, MBA, a former AGA Governing Board member — to establish a regular cadence of meetings with national and regional payors.

Teixeira said UHC framed the decision as part of a shared commitment to simplify systems and allow physicians to spend more time with patients and told AGA it was the organization UHC wanted to inform first.

“A lot of the work we’re doing is not exciting; it’s slogging along, coordinating meetings, continuing the dialogue,” Teixeira said. “Sometimes it’s really slow, and you feel like you’re getting nowhere. And then, all of a sudden, the jam breaks.”

The relationship now runs in both directions, Narramore said. Payors increasingly seek AGA’s clinical expertise and feedback as they develop policies affecting GI care, while AGA invites them, like other stakeholders, to comment during the public-review period for new clinical guidelines. She said AGA has been “pleasantly surprised” that the willingness to engage extends across the major payors, not just UHC.

“They’re one of the biggest payors, so I think it will have an impact,” Teixeira said. “We hope this will lead to changes for the other major payors. It doesn’t mean that we support everything that they do. Change often comes slow, but this is really important progress.”

How the program got here

UHC announced in March 2023 that it would require prior authorization for

61 nonscreening GI endoscopy codes in many commercial plans. AGA made blocking the policy a priority. More than 175 physician groups, patient organizations, and other stakeholders joined the opposition, and the three national GI societies met with UHC days before implementation. On May 31, 2023 — one day before the start date — UHC withdrew the requirement and substituted advance notification, which it said would collect data to “accelerate gold carding” for eligible groups.

Because UHC did not deny claims over missed notifications, participation was effectively optional, and AGA continued to oppose the process as duplicative work without demonstrated benefit.

UHC later launched a broader National Gold Card program, but AGA said it has not identified GI groups that received Gold Card status through the endoscopy pathway described during the 2023 dispute.

“So far, we haven’t found any GIs who have received the elusive Gold Card through that pathway,” Narramore said.

Under UHC’s national program, qualifying groups still submit advance notification for designated Gold Card services. The Sept. 1 GI notice does not move endoscopy into that program. It ends advance notification altogether, effectively making the proposed GI-specific pathway moot.

“We can move the needle.”

Narramore encouraged members to track whether the change improves their day-to-day operations and share what they find with AGA. Many members see payors as obstructionists, she said, and the systems they navigate are genuinely burdensome, which is why the announcement matters beyond its specifics. “We can move the needle, and this is proof,” she said.

Teixeira recalled a time when members felt differently. “Years ago, there was this sense from members that they were just defeated, like we have no leverage,” she said. That changed with the UHC fight: “We have to do what we can to push back when necessary, but it’s also important to work with them,” she said. “We bring credibility to the table. We have the expertise on many issues that they don’t, so it’s in their interest to engage with us.”

GI faces another round of Medicare cuts under proposed 2027 rules

Proposed rules would trim GI endoscopy payment in every setting and pay additional same-day services at 50%.

By [Bob Alaburda](#)

Gastroenterologists would see lower Medicare payment across nearly every site of service in 2027 under proposed rules from the Centers for Medicare & Medicaid Services (CMS), with the deepest physician cuts landing on office-based endoscopy and the steepest facility cuts on upper GI procedures performed in ambulatory surgery centers.

CMS released the CY 2027 Medicare Physician Fee Schedule proposed rule (CMS-1848-P) on July 14, following the CY 2027 Hospital Outpatient Prospective Payment System and ASC proposed rule on July 2. The comment period closes Sept. 14, with final rules expected in the fall.

Most of the payment movement is familiar — an expiring congressional increase, another year of practice expense revisions. The genuinely new item is a policy CMS proposed and abandoned in 2019 and has now revived: paying additional same-day services at 50% when an E/M visit and a procedure are reported together. It would reach a small share of endoscopy claims, but cut deeply into the ones it touches.

Conversion factors fall as a temporary increase expires

Beginning in 2026, statute requires CMS to maintain two conversion factors, one for qualifying participants in advanced alternative payment models and one for everyone else. For 2027, CMS proposes \$33.17 for qualifying APM participants, a decrease of \$0.40, or 1.19%, and \$32.84 for non-qualifying practitioners, a decrease of \$0.56, or 1.68%.

The math is less about a new cut than an expiring one. Statutory updates add 0.75% for qualifying APM participants and 0.25% for everyone else, and CMS applies an estimated 0.53% adjustment for proposed work RVU changes. Offsetting those is the expiration of the one-year 2.5% conversion factor

increase Congress enacted for 2026 under Public Law 119-21.

Where the cuts land in GI

Physician payment reductions are larger in the office than in the facility setting, according to AGA, which estimates an average 5% decline for office-based endoscopy against an average 3% decline for endoscopy in ASCs and hospital outpatient departments, where most endoscopy is performed. GI testing services follow the same pattern, with office-based testing down roughly 5% and facility-based testing down roughly 3%. The American College of Gastroenterology puts the facility figure at about 3% as well.

Those reductions land on top of last year's. In 2026, CMS applied a 2.5% efficiency adjustment to the work RVUs of non-time-based codes and revised its practice expense methodology in a way that raised physician payment for office-based procedures while cutting it in ASC and HOPD settings, an effort to steer care toward lower-cost sites. AGA put the combined 2026 effect at an average 8% cut for facility-based GI endoscopy and an average 16% increase for office-based endoscopy — though it notes most GI practices could not restructure quickly enough to capture that office-side gain. The 2027 proposal would erode part of it for practices that did.

Facility payment is a separate stream, and it moves differently. Under the OPPI and ASC proposed rule, ASCs and hospital outpatient departments meeting quality reporting requirements would receive an overall 2.4% facility payment increase. GI does not share evenly in it. AGA attributes proposed changes to the ASC weight scalar, a budget-neutrality adjustment factor, for an approximately 8% decline in ASC payment for most upper GI endoscopies and a 3% decline for lower GI endoscopies, while payment for GI endoscopy stent placement codes would rise 16%. ACG estimates the aggregate ASC decline for many GI procedures at about 2%.

Practice expense drives the cuts

For the second consecutive year, CMS proposes revising its indirect practice expense calculations, though by a different route than in 2026. The agency would phase out the step anchoring specialty-level PE RVUs to practice expense per hour data from 2007 or earlier, replacing it with a stabilizer meant to limit year-to-year volatility.

CMS also proposes capping annual increases or decreases in a code's PE RVU at 5%. As AGA points out, the cap slows the pace of change without limiting its eventual magnitude: codes whose

values under the new methodology differ by more than 5% would keep adjusting incrementally in later years, including after the two-year phaseout of the Indirect Practice Cost Index concludes in CY 2028. The PE RVUs shown for 2027 may not reflect where a code ultimately lands.

Work RVUs, by contrast, are generally unchanged, which is a meaningful shift from 2026's efficiency adjustment that CMS justified on the reasoning that physicians grow more efficient over time. Because the agency may apply that adjustment every three years, AGA notes the next application could come as early as 2029.

G2211 would become a modifier

CMS proposes replacing HCPCS code G2211, the visit complexity add-on used in GI for ongoing care of conditions such as advanced liver disease, Crohn's disease, and ulcerative colitis, with a two-digit modifier appended to the base E/M code. The placeholder modifier, MOD1, would increase payment for the associated E/M code by 16%, applying the same percentage across all visit levels rather than the current flat rate.

The swap from a flat amount to a percentage makes the effect uneven. AGA's analysis finds that lower-level visits reported with MOD1 would be paid less than they are today with G2211, while some higher-level visits would be paid marginally more. A second modifier, MOD2, would add 32% but be limited to practitioners in qualifying accountable care organizations, including Shared Savings Program and Long-term Enhanced ACO Design model participants, a group that would exclude most gastroenterologists.

The operational lift may matter more than the dollars. Practices currently reporting G2211 would need EHR updates, coding education, modifier logic, billing edits, and compliance review.

Same-day E/M reductions

CMS proposes reducing payment when a separately identifiable office or outpatient E/M visit is furnished on the same day as a procedure with a 0-, 10-, or 90-day global period by the same physician or a physician in the same practice. The highest-paid service would be paid in full and every other same-day service at 50%. The agency argues that efficiencies exist when the same physician provides an E/M service alongside a global-period procedure and that current methodology likely pays twice for the same work.

ACG warns that gastroenterologists who frequently bill an E/M visit

with a procedure could see lower reimbursement. AGA's read is that the aggregate revenue effect on endoscopy should be limited, because Medicare data show same-day E/M billing is uncommon, ranging from roughly 0.3% to 0.7% of claims depending on the code. Where the policy does apply, the per-claim hit is substantial: AGA calculates a combined RVU reduction of approximately 16% to 25% for EGD with biopsy (CPT code 43239) reported with higher-level new and established patient E/M codes, and approximately 10% to 21% for colonoscopy with snare polypectomy (CPT code 45385).

Remote monitoring rules tighten

CMS proposes limiting remote therapeutic monitoring to established patients, requiring a separately reportable initiating visit before remote physiologic or therapeutic monitoring begins, and paying for these services only when they are furnished by clinical staff employed by the practice rather than by contractors. The agency is also seeking comment on bundling the RPM and RTM code families into four new HCPCS G codes, citing recent Office of Inspector General findings it says cannot be resolved within the current coding structure.

AGA identifies the contractor restriction as the most operationally significant of the three, since it would reach arrangements that rely on outside vendors for monitoring infrastructure, patient outreach, or clinical staffing. Practices using vendor-supported remote monitoring for chronic GI conditions would need to assess whether those models remain compliant.

New ESD values, fewer GI quality measures

Not everything in the rule cuts against GI. CMS proposes physician work RVUs of 15.00 for upper GI endoscopic submucosal dissection and 16.38 for lower GI ESD, which would make them the highest-valued work in GI endoscopy when the codes take effect in 2027.

CMS also proposes removing two quality measures with direct GI relevance: appropriate follow-up interval for normal colonoscopy in average-risk patients, and repeat screening or surveillance colonoscopy recommended within one year because of inadequate bowel preparation. Separately, MIPS Value Pathways would become mandatory beginning with the CY 2029 performance period for gastroenterologists not participating in an advanced APM. ACG argues the combination narrows the set of measures most applicable to practicing gastroenterologists.

Six-trial analysis finds no new upadacitinib safety signals in IBD

Shingles rates climbed with dose — 6.6 events per 100 patient-years at 30 mg vs. 1.9 with placebo — while blood clots, cardiovascular events, and cancers stayed uncommon.

By Doug Brunk



Long-term upadacitinib treatment was linked to low rates of blood clots, major cardiovascular events, and cancer in patients with moderate to severe ulcerative colitis (UC) or Crohn's disease (CD). However, shingles (herpes zoster) and some laboratory abnormalities occurred more often with upadacitinib than with placebo, according to an analysis of six clinical trials.

The safety analysis, published in *Clinical Gastroenterology and Hepatology*, combined data from three ulcerative colitis and three Crohn's disease trials of the oral Janus kinase (JAK) inhibitor. During induction, 725 patients received placebo and 1,393 received upadacitinib 45 mg once daily. During maintenance and long-term follow-up, 468 received placebo, 471 received upadacitinib 15 mg, and 480 received 30 mg. Total exposure to the 15-mg and 30-mg doses reached 5,149 patient-years.

The study authors tracked side effects that occurred after patients received at least one study dose. Long-term event rates were reported per 100 patient-years. Safety outcomes included serious and opportunistic infections, shingles, gastrointestinal perforation, cancer, major cardiovascular events, blood clots, and laboratory abnormalities.

During induction, 61% of patients taking upadacitinib 45 mg experienced a side effect compared with 57% taking placebo. Serious side effects occurred in 6% of the upadacitinib group and 7% of the placebo group, and 4% vs. 6% stopped treatment because of side

effects. No deaths occurred. Acne was more common with upadacitinib than placebo (6% vs. 1%), but most cases were mild.

Among patients who responded to induction and continued into maintenance or long-term follow-up, overall side effect rates were lower with upadacitinib than placebo. Serious side effects and side effects that led patients to stop treatment also occurred less often with both the 15-mg and 30-mg doses than with placebo.

Side effects of particular concern with JAK inhibitors remained uncommon. Blood clot rates were 0.3 and 0.4 events per 100 patient-years with upadacitinib 15 mg and 30 mg, respectively, with no events in the placebo group. Seven blood clots occurred with upadacitinib, mostly in patients with existing risk factors. Rates of major cardiovascular events and cancer were also low and similar across groups.

Shingles became more common as the upadacitinib dose increased. During maintenance and long-term follow-up, rates were 1.9 events per 100 patient-years with placebo, 3.9 with the 15-mg dose, and 6.6 with the 30-mg dose. Most cases were mild to moderate and occurred in patients who had not previously had shingles or been vaccinated against it. Rates were somewhat higher in patients with CD.

Upadacitinib was also associated with higher rates of neutropenia, lymphopenia, creatine phosphokinase elevation, and hepatic disorders. Most liver-related events were mild or

moderate, were not serious, and did not lead patients to stop treatment. No cases of severe drug-related liver injury were identified.

Safety findings were generally similar in patients younger than 65 years and those aged 65 years or older, although few older patients were included. The study also included few patients with other health conditions, no patients older than 75 years, and shorter follow-up with placebo than with upadacitinib. The authors said these limitations may make the findings less applicable to broader patient populations and called for more long-term, real-world data.

"No new or unexpected safety risks

were reported with [upadacitinib], suggesting an overall acceptable safety profile in patients with moderately to severely active UC and CD who are undergoing long-term therapy with [upadacitinib]," the authors concluded.

AbbVie funded and designed the trials, analyzed the data, and supported medical writing; investigators and the sponsor jointly collected and interpreted the data. Multiple authors reported financial relationships with AbbVie and other pharmaceutical companies; nine were AbbVie employees with potential stock or options, and one was employed by AbbVie during the analysis.

GI & Hepatology News asked Jason Ken Hou, MD, MS, FACP, a gastroenterologist at Baylor College of Medicine, Houston, and medical director of IBD at the Michael E. DeBakey VA Medical Center, to weigh in on the study results.

Why do these findings matter?

Dr. Hou: This study is important as there have been potential safety concerns with the Janus kinase inhibitor class of medication due to prior data from tofacitinib regarding thrombosis and upadacitinib regarding increased risk of shingles. Randomized trials are powered for efficacy and may miss subtle safety signals so combined safety analyses may uncover or highlight additional safety concerns. Randomized controlled trials are also helpful for safety analyses as there is a placebo group for comparison which is an advantage over observational studies.

How might the findings influence clinical practice?

Dr. Hou: The findings are encouraging that no new safety signals emerged with combined analyses.

Where are the knowledge gaps, and what still needs investigation?

Dr. Hou: Randomized controlled trials are too short and small to evaluate some risks, including risks of malignancy which require longer follow up and sample sizes.

Is there anything else you'd like to say about this work?

Dr. Hou: The study provides additional reassurance on the relative safety of upadacitinib for UC and CD. The risk of herpes zoster appears more pronounced at the 30 mg vs. 15 mg daily doses. Acne risk occurred across indications in induction, but the authors note the rate causing drug discontinuation was low. There were several lab abnormalities, including neutropenia and lymphopenia, and creatine kinase elevations that were noted to be higher than placebo, so lab monitoring is important for patients on upadacitinib. However, those abnormalities did not appear to be severe.

Dr. Hou was a site principal investigator for the phase 3 upadacitinib trials in UC and CD. He is also an associate editor for Clinical Gastroenterology and Hepatology.



Aspirin trial supports 100 mg daily for Lynch syndrome

"There are no indications for 600 mg."

By Doug Brunk

Patients with Lynch syndrome who took 100 mg of aspirin daily had a similar risk for developing Lynch syndrome-related cancers as those taking 600 mg daily during about five years of follow-up, while experiencing fewer side effects and fewer serious bleeding events. Although the study did not meet all of its planned statistical criteria to prove that the lower dose worked as well as the higher dose, the results suggest that 100 mg daily may provide a good balance between cancer prevention and safety. The study was published in *The Lancet Gastroenterology & Hepatology*.

Lynch syndrome is the most common inherited cause of colorectal cancer. Earlier results from the CAPP2 trial showed that taking 600 mg of aspirin daily lowered the risk for colorectal cancer, but concerns about bleeding and hesitation to prescribe higher doses led investigators to test whether lower doses could provide similar protection in the CaPP3 trial.

The multicenter, randomized, double-blind trial enrolled 1,879 adults with Lynch syndrome at clinical genetics centers in the United Kingdom, Australia, Finland, Israel, and Spain between 2014 and 2019. Patients were randomly assigned to take 100 mg, 300 mg, or 600 mg of aspirin daily. The assigned dose remained blinded for the first two years, followed by three years of open-label treatment. The primary outcome was the development of new cancers associated with Lynch syndrome.

After excluding 13 participants, the intention-to-treat analysis included 1,866 patients, who were followed for a median of 66 months. During that time, 176 patients developed 216 Lynch syndrome-related cancers, including 83 colorectal cancers. The fewest Lynch syndrome cancers occurred in the 100 mg group, with 57 cases, compared with 75 cases in the 300 mg group and 84 cases in the 600 mg group, or 39% of all cancers.



John Burn, MD, FMedSci

In the intention-to-treat analysis, the 100 mg dose met the study's predefined criteria for performing as well as the 600 mg dose in delaying the first Lynch syndrome-related cancer and reducing the overall number of cancers. However, the 100 mg dose did not meet those criteria in the per-protocol analysis for time to first cancer, meaning the study could not formally conclude that it was equivalent to the higher dose across all planned analyses. The 300 mg dose did not meet the study's noninferiority criteria in either analysis.

Secondary analyses showed similar results for colorectal cancer. During follow-up, 83 participants developed colorectal cancer: 21 in the 100 mg group, 30 in the 300 mg group, and 32 in the 600 mg group. Although the study again did not consistently meet its predefined criteria to show that the lower dose performed as well as the higher dose, the investigators said the 100 mg dose produced comparable colorectal cancer outcomes to the 600 mg dose.

"In non-inferiority trials, the per protocol group has added significance to guard against the potential for widespread non-compliance, making all treatment groups similar," first author John Burn, MD, FMedSci, professor of clinical genetics at Newcastle University, Newcastle upon Tyne, United Kingdom, told *GI & Hepatology News*. "This is very unlikely in this motivated study population and the colorectal cancer rate in the 600mg group almost exactly matched that seen in the 600mg group in CAPP2."

For practicing physicians, Dr. Burn said: "We now recommend 75-100 mg (varies by country, but bio equivalent) for adults with Lynch syndrome. People who are significantly overweight should consider doubling that dose. There are no indications for 600 mg."

Safety outcomes favored the lower dose. During the blinded phase, 25% of patients taking 100 mg of aspirin

GI & Hepatology News invited Dr. Burn to comment on the work.

How should clinicians counsel patients about the tradeoff between the lower bleeding risk seen with 100 mg and the fact that formal noninferiority was not met in every analysis?

Dr. Burn: The paper expands on this, but a simple guide is that after an average of over seven years, the people on the lowest dose had the fewest cancers. Noninferiority design is very challenging, especially in prevention. The effect kicks in after around four years, so early events are misleading. This probably explains the 300 mg result.

With longer follow-up planned through 10 years, what key unanswered question do you expect those additional data will help resolve?

Dr. Burn: It's highly likely the complete data will tighten the confidence intervals and satisfy any skeptics. We will also drill down on the dose needed to deal with the higher cancer rate in overweight people. We now have data stretching back over three decades supporting the benefit of an anti-platelet aspirin dose and are confident this should now be recommended to all adult carriers under 70. This is now UK policy.

Is there anything else you'd like to say about this work?

Dr. Burn: Our continued work will tap into the new Lynch registry in the UK and we will more than double the patient years of follow up. There is now a plausible mechanism; platelet suppression improves T cell function against these highly immunogenic cancers.

"For clinicians hesitant to prescribe 600 mg of aspirin because of bleeding concerns, the CaPP3 results provide reassuring evidence that much lower doses may achieve similar outcomes for many patients with Lynch syndrome."

reported at least one adverse event, compared with 31% of those taking 600 mg. Bleeding events occurred in 15% and 19% of patients, respectively. No patients in the 100 mg group experienced a serious bleeding event requiring hospitalization, compared with three patients in the 300 mg group and 11 patients in the 600 mg group over five years. Most adverse events were mild to moderate.

The investigators acknowledged several limitations. Follow-up remains relatively short for a cancer prevention trial, with additional follow-up planned

through at least 10 years. Aspirin adherence could not be reliably measured because tablet counts were unreliable, temporary treatment interruptions were not included in the analyses, and some tumors could not be confirmed as Lynch syndrome-related because tissue samples were unavailable.

Cancer Research UK, Bayer Pharma, and Newcastle Hospitals NHS Foundation Trust funded the study, with additional support for participating international sites. The authors reported no competing interests.

Noninvasive neuro-modulation reduces fecal incontinence in phase 3 trial

Continued From Page 1 ➔

Dr. Rao and colleagues randomly assigned 109 adults whose fecal incontinence had not improved with conservative treatment to receive 2,400 magnetic pulses, 3,600 pulses, or sham magnetic pulses treatment. The pulses were delivered to four sites in the lower back once a week for six weeks. Patients and researchers assessing the results did not know which treatment was given, but the researcher administering it did.

The main outcome was the proportion of patients who had at least half as many fecal incontinence episodes as they did before treatment. Researchers also measured how many patients had at least a 75% reduction, days without incontinence, symptom severity, quality of life, anorectal function, and nerve function. All randomized patients were included in the analysis.

Among patients receiving 2,400 magnetic pulses, 66% had at least half as many fecal incontinence episodes after treatment, compared with 81% of those receiving 3,600 pulses and 32% receiving sham treatment. Patients receiving 2,400 pulses had nearly four times the odds of responding as those receiving sham, while those receiving 3,600 pulses had more than eight times the odds. The two active doses did not differ significantly.

Fecal Incontinence Severity Index scores improved by 8.6 points with 2,400 pulses and 5.6 points with 3,600 pulses, compared with 1.4 points with sham treatment. Patients receiving TNT also reported improvements in all four areas of quality of life measured, although the differences between the treatment groups were not significant.

The treatment also appeared to improve nerve and muscle function. Nearly 90% of patients had nerve damage in the lower back and sacral region at the start of the study. After TNT, nerve signals traveled significantly faster in most pathways involved in bowel control compared with sham treatment, indicating improvements in neuropathy. Patients receiving TNT

also showed stronger anal squeeze pressures, indicating improvements in muscle control.

No serious side effects were linked to the treatment. Two patients in each group reported temporary back pain, while tingling or numbness and urinary urgency were each reported by one patient receiving TNT. Three patients were hospitalized for serious events that investigators determined were unrelated to treatment. Overall, 94% of patients completed their assigned treatments.

The authors noted that it remains unclear how long the benefits last and whether 3,600 pulses are more effective than 2,400. Limitations included relatively few men, a treatment administrator who knew which therapy

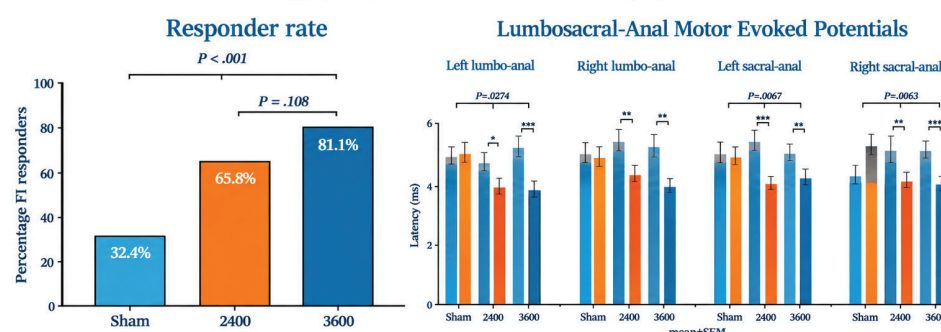
patients received, and possible low-level magnetic stimulation from the sham treatment.

Colleen Parker, MD, FRCPC, a staff gastroenterologist at University Health Network, Toronto, who was asked to comment on the study, said she was impressed by the response rate among patients who received active treatment. "The particular strength of this study is that not only does it demonstrate improvement clinically but also demonstrates physiologic changes in patients that respond," Dr. Parker said. "The therapy appears to be well tolerated with no serious adverse events, which further adds to the potential appeal of this therapy to both patients and clinicians."

Despite the encouraging results, "further work is needed to determine the durability of this therapy," she added. "The appropriate dose of the stimulation needs to be determined, [as well as] how often and how long sessions need to be to offer clinical benefit, and how long the benefit can last. This does appear to be a promising therapy for patients with a condition that is often difficult to treat. It will be interesting to see how this can be generalized and brought to the clinic."

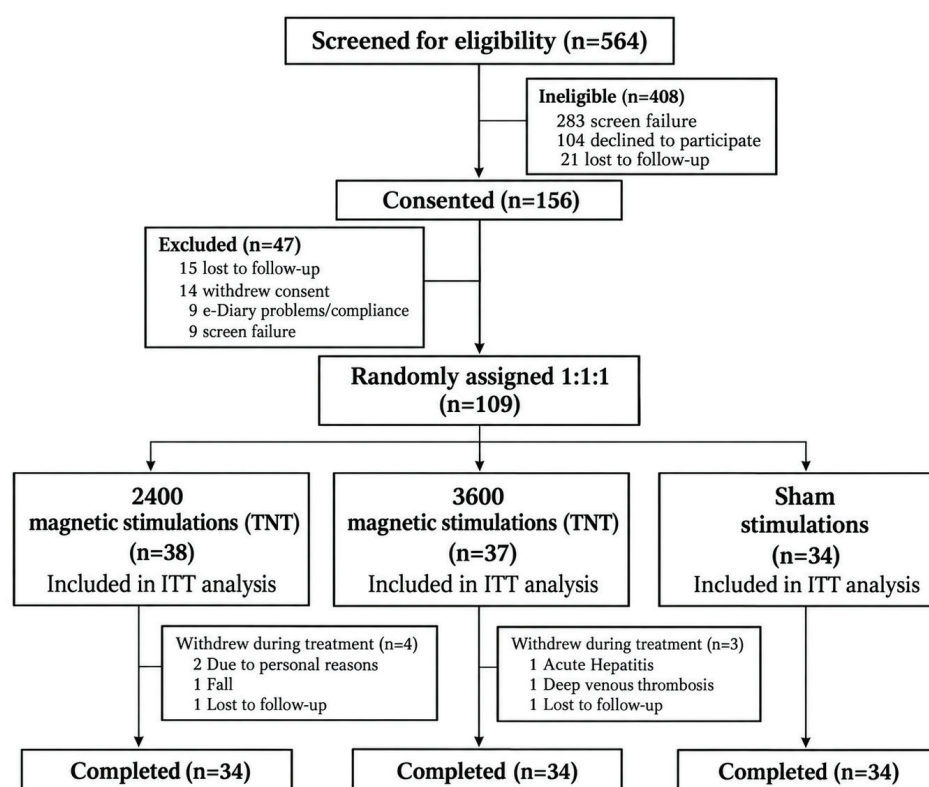
The National Institutes of Health supported the study. Dr. Rao holds a patent for TNT; the remaining authors reported no conflicts of interest. Dr. Parker reported having no disclosures.

Translumbosacral Neuromodulation Therapy (TNT) in Fecal Incontinence (FI): Randomized Trial



TNT, a novel, non-invasive, outpatient treatment was significantly more efficacious than sham in improving symptoms and neuropathy and was safe and well-tolerated in FI patients.

Graphical abstract courtesy of *Gastroenterology*.



Consort flow diagram of study participants. ITT, intention to treat. Table courtesy of *Gastroenterology*.

GI & Hepatology News asked Dr. Rao to put the findings into clinical context.

Where might noninvasive TNT fit in the treatment algorithm for patients with fecal incontinence refractory to conservative therapy?

Dr. Rao: TNT can be administered alongside biofeedback therapy or after biofeedback therapy and certainly before considering invasive procedures such as a dextranomer injection or surgery or sacral nerve stimulation (SNS) implantation. This is an outpatient procedure that takes about an hour, is non-invasive, and well tolerated with very minimal side effects.

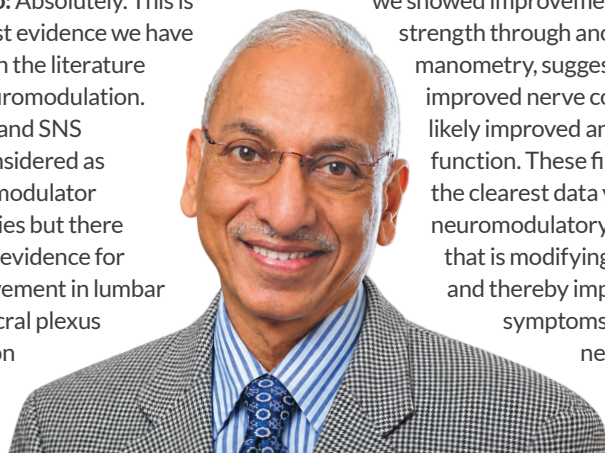
Do the improvements in lumbosacral nerve conduction and anal sphincter function suggest that TNT is modifying the underlying pathophysiology of fecal incontinence?

Dr. Rao: Absolutely. This is the best evidence we have so far in the literature for neuromodulation. Drugs and SNS are considered as neuromodulator therapies but there is little evidence for improvement in lumbar and sacral plexus function

or anorectal neuropathy. Here we found significant improvement and in fact normalization of neuropathy in a majority of patients who received active TNT treatment, whereas those who received sham therapy showed no significant change. Additionally, we showed improvement in muscle strength through anorectal manometry, suggesting that the improved nerve conduction likely improved anal sphincter function. These findings provide the clearest data yet for a neuromodulatory treatment that is modifying the disease and thereby improving symptoms, likely through neuroplasticity.

What additional evidence is needed before TNT could be incorporated into routine clinical practice?

Dr. Rao: This multicenter, sham-controlled study showed conclusively that TNT is efficacious and safe. However, confirmatory studies from other centers will help to corroborate these findings in the future. Also, we are performing additional studies to examine the long-term outcome of TNT and look at other objective metrics of improvement including gut and brain interactions, stool microbiome, salivary gene markers, and to examine the predictive factors for clinical response.



Smartphone hypnotherapy misses noninferiority threshold in IBS trial

In a 230-patient randomized trial, abdominal pain response was 48.1% with in-person hypnotherapy and 33.3% with smartphone-based treatment, although digital therapy may help expand access to gut-directed treatment.

By Meg Barbor

A self-guided smartphone hypnotherapy program did not meet the prespecified threshold for noninferiority to in-person hypnotherapy for abdominal pain response in patients with irritable bowel syndrome (IBS), according to findings published in *Gut*.

At weeks 13-16, Food and Drug Administration-defined abdominal pain response rates were 48.1% with in-person therapist-delivered hypnotherapy, 33.3% with smartphone-based self-guided hypnotherapy, and 21.8% with online psychoeducation. The response-rate difference between smartphone and in-person hypnotherapy was -14.7 percentage points (95% CI, -29.3 to 0.9). Because the lower confidence bound crossed the

prespecified -10% noninferiority margin, noninferiority was not established.

In an interview with *GI & Hepatology News*, study investigator Daniel Keszthelyi, MD, PhD, of the Department of Gastroenterology and Hepatology at Maastricht University Medical Centre+ and Maastricht University, said gut-directed hypnotherapy should be considered earlier in IBS care.

"Gut-directed hypnotherapy has traditionally been considered a therapeutic entity for patients with IBS who had not experienced sufficient symptom resolution to other traditional treatments including dietary adjustment, such as the low-FODMAP diet, or drugs, like antispasmodics, yet it ought to be considered as first-line therapy," Dr. Keszthelyi said.

He said this is particularly relevant because hypnotherapy "practically has no side effects." However, broader use has been limited by the availability of trained professionals and reimbursement issues, which may lead patients or clinicians to choose other therapies.

Comparing three approaches

The multicenter, three-arm randomized controlled trial included 230 patients aged 17-73 years with Rome IV IBS. Mean age was 38.2 years, 70.4% were female, 47.0% were treated in primary care, and most had moderate or severe IBS symptom severity at baseline.

Patients were randomly assigned to 12 weeks of online self-guided psychoeducation, smartphone-based self-guided hypnotherapy, or in-person therapist-delivered hypnotherapy.

In-person treatment consisted of

"Gut-directed hypnotherapy has traditionally been considered a later-line treatment for IBS, yet it ought to be considered as first-line therapy."

six biweekly 45-minute sessions using a structured hypnotherapy protocol, plus home exercises for 15-30 minutes per day on five days each week. The smartphone group received the same scripted hypnotherapy sessions through audio delivered by an app and was instructed to use the program for 15-30 minutes per day on five days each week. The psychoeducation group completed interactive online self-guided modules designed to support IBS self-management.

The primary endpoint was abdominal pain response by FDA criteria, defined as at least a 30% reduction from baseline in the weekly average of worst daily abdominal pain during at least two of four post-treatment weeks. Patients were assessed at weeks 13-16 and again approximately six months after treatment.

Response rates

Although the primary response rate was 14.7 percentage points lower with smartphone-based therapy than with in-person treatment, the adjusted direct comparison between the two groups was not statistically significant (OR, 1.86; 95% CI, 0.94-3.68; $P=.076$).

A sensitivity analysis using multiple imputation for missing data also did not establish noninferiority. In that

analysis, FDA-defined response rates were 51.4% with smartphone-based hypnotherapy and 56.4% with in-person hypnotherapy, for a difference of -5.0 percentage points (95% CI, -22.7 to 12.8). Although the point estimate was within the prespecified margin, the lower confidence bound remained below -10%.

In-person hypnotherapy was more effective than psychoeducation at weeks 13-16 (OR, 3.48; 95% CI, 1.68-7.20; $P<.001$).

At six-month follow-up, response rates were 40.3% with in-person hypnotherapy, 33.3% with smartphone-based hypnotherapy, and 14.1% with psychoeducation. Both hypnotherapy groups were more effective than psychoeducation at that point: OR, 4.68 (95% CI, 2.07-10.57; $P<.001$) for in-person therapy and OR, 3.11 (95% CI, 1.37-7.09; $P=.007$) for smartphone-based therapy. The difference between the two hypnotherapy groups was not statistically significant at six months (OR, 1.51; 95% CI, 0.75-3.03; $P=.253$).

Among patients who responded at week 16, sustained response at six months occurred in 70.3% of the in-person group, 64.0% of the smartphone group, and 47.1% of the psychoeducation group.

Secondary outcomes also favored both hypnotherapy approaches over



psychoeducation. Using a reduction of at least 50 points on the IBS Symptom Severity Scale, response rates at week 12 were 61.0% with in-person hypnotherapy, 53.3% with smartphone-based hypnotherapy, and 28.2% with psychoeducation. Both hypnotherapy groups also showed significantly greater reductions in IBS Symptom Severity Scale scores over time than the psychoeducation group.

There were no significant between-group treatment effects on psychological symptoms after correction for multiple comparisons.

Access may shape use in practice

Although in-person therapy had the highest primary response rate, the findings suggest smartphone-based delivery could expand access to a therapy otherwise limited by workforce and cost barriers, Dr. Keszthelyi said.

"The key takeaway is that novel modes of hypnotherapy delivery, such as a smartphone-based self-delivered version, can be very helpful in particular in rural areas where the availability of therapists is limited," he said.

The study authors similarly wrote that smartphone-based self-guided hypnotherapy may represent a viable treatment option for patients with IBS because it can be used regardless of whether a certified therapist is nearby or whether patients can afford therapist-led treatment.

The authors suggested differences in adherence may partly explain the difference in response rates. Self-reported adherence was highest with in-person hypnotherapy, at 85.7% for therapist visits and 72.7% for home exercises, compared with 62.7% for smartphone-based hypnotherapy and 65.4% for psychoeducation.

In the per-protocol analysis, FDA-defined abdominal pain response rates

were closer between the hypnotherapy groups: 51.5% with in-person therapy, 48.9% with smartphone-based therapy, and 31.4% with psychoeducation.

The authors noted that a hybrid model, such as one or two face-to-face sessions followed by digital delivery, may warrant further study as a way to improve adherence while maintaining accessibility.

Screening remains important

Dr. Keszthelyi cautioned that smartphone-based access should not mean patients simply download an app and begin hypnotherapy without clinical input.

"Patients should not directly just download a hypnotherapy app and get started," he said. "A health care professional should first ascertain whether hypnotherapy is indeed the preferred therapy for the individual in question."

In the trial, patients were screened using questionnaires, particularly with respect to previous trauma, Dr. Keszthelyi said. Patients with elevated anxiety or depression scores were evaluated by an investigator and excluded if anxiety or depression was present because they might be better served by more personalized treatment. The study authors also noted that patients with a history of trauma may relive negative experiences during hypnosis.

"During hypnosis, patients can potentially relive certain traumatic experiences; therefore, these should first be addressed before proceeding with hypnotherapy," Dr. Keszthelyi said.

Adverse events were reported significantly more often in both hypnotherapy groups than in the psychoeducation group. The most

commonly reported events were gastrointestinal symptoms, fatigue, and headache or neck pain. The authors characterized the events as mild, reported that none led to study withdrawal, and said the relatively high number of reports may have reflected daily adverse-event monitoring during treatment.

Study limitations

The authors noted several limitations. Recruitment was slower than expected, partly because of disruptions during the COVID-19 pandemic, and fewer patients completed treatment than planned. The 18-week run-in, treatment, and post-treatment period may also have contributed to missing daily diary data, and a cyberattack caused an additional period of missing data for some participants.

Missing observations were classified as nonresponse in the primary analysis, which the authors said may have underestimated response rates because responder rates were higher after multiple imputation. They also noted potential selection bias because patients willing to participate in a hypnotherapy trial may have had more favorable attitudes toward the treatment.

The trial was funded by ZonMw, the Netherlands Organisation for Health Research and Development. Dr. Keszthelyi reported research funding from ZonMw, Rome Foundation, Horizon Europe, Horizon 2020, and the Dutch Foundation for Gastroenterology-Hepatology, and a speaker fee from Rome Foundation paid to his host institute. The remaining authors reported nothing to declare.



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FDA expands Stelara approval to pediatric ulcerative colitis

The label expansion makes ustekinumab the first approved therapeutic monoclonal antibody that does not target tumor necrosis factor- α for both main forms of pediatric inflammatory bowel disease, according to the FDA.

By Bob Alaburda

The FDA has approved Stelara (ustekinumab) injection for the treatment of moderately to severely active ulcerative colitis in pediatric patients aged 2 years and older, the agency announced Aug. 28.

The expansion follows the April 15, 2026, approval of ustekinumab for moderately to severely active Crohn's disease in pediatric patients aged 2 years and older. With both pediatric indications in place, Stelara is the first approved therapeutic monoclonal antibody that does not target human tumor necrosis factor- α (TNF) for the two main forms of pediatric inflammatory bowel disease, according to the FDA.

What supported the indication

The FDA said the safety and effectiveness of Stelara for moderately to severely active UC in children was supported by evidence from adequate and well-controlled studies in adults with UC, pharmacokinetic and safety data from pediatric patients with Crohn's disease aged 2 to 17 years, and additional safety, efficacy, and pharmacokinetic data from

a 52-week study in 112 pediatric patients with UC aged 3 to 17 years.

That 52-week study is the phase 3 UNIFI Jr trial (NCT04630028). According to results published in the *Journal of Crohn's and Colitis*, 112 patients with moderately to severely active UC received a single open-label intravenous induction dose of ustekinumab, and 109 were randomized at week 8 to blinded subcutaneous maintenance therapy every 8 weeks or every 12 weeks for 44 weeks. Seventy-nine patients achieved clinical response at week 8.

Among those 79 induction responders, 32 (40.5%) were in clinical remission at week 52, 52 (65.8%) achieved symptomatic remission, 32 (40.5%) achieved endoscopic improvement, and 32 (40.5%) were corticosteroid-free for at least 90 days, investigators reported. Week-52 remission was higher among patients who had not previously failed a biologic than among those who had, 47.2% vs. 26.9%, a subgroup comparison in which the confidence intervals overlapped.



Safety and designation

The most common adverse reactions in pediatric patients with UC receiving Stelara are nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea, according to the FDA. In UNIFI Jr, serious adverse events occurred in 6.4% of patients (7 of 109) during maintenance therapy, most commonly gastrointestinal disorders.

Stelara received orphan drug designation for the indication. Approval was granted to Janssen Biotech.

Ustekinumab in adult UC

Ustekinumab targets the p40 subunit shared by interleukin-12 and interleukin-23 and has been approved for adults with moderately to severely active UC since 2019.

AGA's living guideline on the pharmacological management of moderate-to-severe ulcerative colitis addresses adult outpatients and does not make recommendations for pediatric patients. For adults previously exposed to one or more advanced therapies, particularly TNF antagonists, the

guideline groups ustekinumab among the higher-efficacy medications; for adults naive to advanced therapies, it groups ustekinumab among the intermediate-efficacy medications. Guideline panel members reviewed new UC evidence in July 2025 and in March 2026 and issued no new or amended recommendations.

Other pediatric options under study

The approval adds to a small set of advanced therapies labeled for children with UC. In December 2025, Jess L. Kaplan, MD, of the Division of Pediatric Gastroenterology and Nutrition at Mass General for Children, Boston, told *GI & Hepatology News* that anti-TNF agents were at that time the only FDA-approved biologic or advanced therapy for children with moderate to severe UC. Dr. Kaplan was first author on a phase 2 trial of the interleukin-23 inhibitor mirikizumab in children with UC.

GI & Hepatology News reported in January 2026 on real-world outcomes with off-label upadacitinib in 48 patients younger than 18 years with Crohn's disease or UC, presented at the 2026 Crohn's & Colitis Congress.

First RAS-targeted therapy approved for metastatic pancreatic cancer

Daraxonrasib roughly doubled median overall survival compared with chemotherapy in previously treated patients in the phase 3 RASolute 302 trial.

by Bob Alaburda

The FDA on Aug. 26 approved daraxonrasib (Rasonque, Revolution

Medicines) for adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy. It is the first approved therapy that directly targets RAS in the most common form of pancreatic cancer.

Daraxonrasib is an oral, once-daily RAS(ON) multi-selective inhibitor. Unlike the mutation-specific KRAS inhibitors already approved in colorectal and lung cancer, which act on a variant rarely seen in pancreatic tumors, daraxonrasib suppresses signaling from both mutant and wild-type RAS in its active, GTP-bound state. Aberrant RAS signaling drives the large majority of pancreatic ductal adenocarcinoma (PDAC), with activating mutations present in more than 90% of tumors.

The approval rests on RASolute 302 (NCT06625320), a global, randomized, open-label phase 3 trial that enrolled

500 patients with previously treated metastatic PDAC. Participants received either daraxonrasib 300 mg once daily (n = 248) or investigator's choice of one of four cytotoxic chemotherapy regimens (n = 252). The trial enrolled patients across a range of RAS variants as well as patients with no identified RAS mutation, with dual primary endpoints of overall survival (OS) and blinded independent central review-assessed progression-free survival (PFS) in the RAS G12 subgroup.

In the intention-to-treat population, median OS was 13.2 months with daraxonrasib versus 6.7 months with chemotherapy (HR, 0.40; 95% CI, 0.30-0.53; $P < .0001$) — a 60% reduction in the risk of death. Median PFS was 7.2 months versus 3.6 months (HR, 0.49; 95% CI, 0.38-0.64; $P < .0001$), and objective response rates were 31.6% versus 11.2%. Results in the RAS G12 population were essentially superimposable, with a median OS of 13.2 months versus 6.6 months and an identical

hazard ratio of 0.40.

Patient-reported outcomes favored the oral agent as well. Time to deterioration in cancer-related pain (HR, 0.51) and in global health status and quality of life (HR, 0.60) were both significantly delayed relative to chemotherapy.

Grade 3 or higher treatment-related adverse events occurred in 43.6% of patients on daraxonrasib versus 57.5% on chemotherapy, and the toxicity profiles differed in kind as well as degree. The most frequent grade 3 or higher events with daraxonrasib were rash (14%) and stomatitis (12%), compared with neutropenia (28%), anemia (16%), and thrombocytopenia (10%) on chemotherapy. Discontinuation for treatment-related toxicity occurred in 1.2% of the daraxonrasib arm versus 11.2% of the chemotherapy arm. One grade 5 treatment-related event, a case of pneumonitis, occurred in the daraxonrasib arm.

FDA approves second blood-based colorectal cancer screening test

Freenome's SimpleScreen CRC detected roughly 8 in 10 cancers in the PREEMPT CRC trial — but just 13.7% of advanced precancerous lesions, the performance gap that keeps blood tests out of guideline-preferred status.

by Bob Alaburda

The FDA has approved SimpleScreen CRC, a cell-free DNA blood test for colorectal cancer screening in average-risk adults aged 45 years and older, making it the second blood-based test cleared for the indication after Guardant Health's Shield in 2024.

The agency's decision on the premarket approval application is dated July 24, 2026.¹ Freenome, which developed the test, and Abbott, which holds exclusive U.S. commercialization rights, announced the approval July 27.² Abbott expects to launch the test this fall.

Under the approved labeling, SimpleScreen CRC is indicated for average-risk adults aged 45 years and older who

have been referred for screening by a health care professional. A positive result should be followed by colonoscopy. The FDA approval order states explicitly that the test is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.¹

Approval rests on PREEMPT CRC, a prospective, multicenter study that enrolled 48,995 asymptomatic, average-risk adults aged 45-85 years at more than 200 U.S. sites, all of whom were scheduled for screening colonoscopy. In the evaluable cohort of 27,010 participants, the test detected colorectal cancer with 79.2% sensitivity and showed 91.5% specificity for advanced colorectal neoplasia, using colonoscopy with histopathology as the reference standard. Sensitivity for advanced precancerous lesions (APLs), a secondary endpoint, was substantially lower. Results were published online in JAMA in June 2025.³

The figures cited in the approval announcement come from a prespecified analysis weighted to the U.S. Census age and sex distribution: 81.1% sensitivity for colorectal cancer, 13.7% sensitivity for APLs, including 30.7% for APLs with high-grade dysplasia, and 90.4% specificity for advanced colorectal neoplasia.²

Guidelines still rank blood tests last

In a statement issued in June, AGA said colonoscopy remains the strongest option because it is the only test that can both catch cancer early and prevent it, since precancerous polyps can be removed during the same procedure. AGA

called stool-based testing a reasonable alternative when colonoscopy is not available or feasible, provided patients understand that an abnormal result requires follow-up colonoscopy and that testing must be repeated at recommended intervals. Blood tests, the association said, should be approached with caution.⁴ The statement directs clinicians to AGA's 2025 clinical practice update in Clinical Gastroenterology and Hepatology on the current role of blood tests in screening.⁵

The American Cancer Society's 2026 screening guideline update, published in May in CA: A Cancer Journal for Clinicians, added blood-based testing as a recommended but explicitly nonpreferred category, advising it only for patients who decline or do not complete a stool-based test or visual examination. The guideline development group cited lower sensitivity for APLs and stage I cancers — noting that confidence intervals around the stage I estimate are wide — and uncertainty about optimal screening intervals.⁶

ASGE reached a similar position. In its position statement on blood-based screening, the society said simulation models project higher colorectal cancer incidence and mortality if patients shift to blood tests from colonoscopy or stool-based testing, an effect it attributed mainly to the low sensitivity of blood tests for APLs.⁷

Freenome said the test meets Medicare coverage criteria with approval, and that it expects SimpleScreen CRC to be added to the ACS guideline by name.² The May guideline named only Shield

among blood tests, as SimpleScreen CRC was still under FDA review at publication.⁶

A next-generation assay

The premarket approval (PMA) covers the first-generation assay Freenome submitted in August 2025.¹ On July 9, the company reported top-line results for an updated version that improved APL sensitivity to 18.2% and high-grade dysplasia sensitivity to 41.9%, with 80.4% sensitivity for colorectal cancer at 90% specificity. Freenome's modeling projected that those gains would yield 7.7% more life-years gained and 9.5% fewer colorectal cancer cases and deaths per 100,000 people screened, compared with the first-generation test.⁸ That version requires a supplemental PMA and is not yet approved.

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New guideline urges earlier referral for pediatric liver transplant

New recommendations emphasize earlier referral, standardized multidisciplinary evaluation, equitable organ access and disease-specific transplant decision-making.

By Doug Brunk



Vicky Lee Ng, MD, FRCPC

A new practice guideline recommends earlier referral of children with advanced liver disease for liver transplant evaluation, calls for a standardized multidisciplinary assessment and places greater emphasis on psychosocial, developmental and health equity issues throughout the transplant process. It also updates recommendations for children with acute liver failure, liver tumors, inherited metabolic disorders and other conditions that may require liver transplantation.

The guideline, published in *Hepatology*, was developed by the American Association for the Study of Liver Diseases in collaboration with the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition and the American Society of Transplantation. It updates the societies' 2014 recommendations and includes 90 evidence-based recommendations covering the pediatric liver transplant evaluation process, from referral through waitlisting and organ allocation.

"Advances in immunosuppression, medical care, surgical techniques, living donation and outcomes have expanded both who can benefit from transplantation and how we think about the timing of referral and evaluation," corresponding author Vicky Lee Ng, MD, FRCPC, medical director of the Pediatric Liver Transplantation, Transplant and Regenerative Medicine Center at the Hospital for Sick Children, Toronto,

Ontario, Canada, told *GI & Hepatology News*. "Yet despite these advances, there has been considerable variation across centers in how children are evaluated for transplantation. This guideline seeks to provide an evidence-informed framework that promotes consistency while recognizing that every child and every family is unique."

The guideline recommends a standardized transplant evaluation led by a multidisciplinary team that includes pediatric hepatologists, transplant surgeons, infectious disease specialists, anesthesiologists, intensivists, psychologists, social workers, dietitians, pharmacists, rehabilitation specialists, child life experts and transplant coordinators. In addition to determining whether a child is medically and surgically eligible for transplantation, the team should assess family readiness, developmental needs, psychosocial well-being and barriers that could affect transplant success.

"Transplant evaluation is far more than deciding whether a child is a candidate," Dr. Ng said. "It is a process of identifying what is needed to help every child achieve the best possible outcome." She added that working to develop this guideline "reinforced for me that transplant evaluation is best viewed as a longitudinal process rather than a single consultation. It has also changed how I frame those early conversations with families. Rather than asking, 'Is this child ready for transplantation?' I find myself asking, 'What does this child need to achieve the best possible outcome?' That shift naturally leads to earlier discussions, proactive planning, optimization of nutrition and medical care and stronger partnerships with families."

The authors recommend comprehensive laboratory testing to determine liver disease severity, nutritional status, renal function, blood type and infectious disease risk. For kidney assessment, they recommend estimating glomerular filtration rate using the Chronic Kidney Disease in Children Under 25 equation because serum creatinine alone may underestimate renal dysfunction in children with advanced liver disease.

Abdominal ultrasound with Doppler is recommended as the first-line imaging test, with computed tomography or magnetic resonance imaging reserved mainly for surgical planning. Every child being evaluated should receive cardiopulmonary screening, including electrocardiography and echocardiography. Those with suspected pulmonary hypertension should have right-heart catheterization, and all transplant candidates should

be screened for hepatopulmonary syndrome using pulse oximetry.

The recommendations emphasize that children being evaluated for liver transplantation should receive all age-appropriate vaccines before transplant whenever possible, using accelerated schedules when needed. Household members also should be fully vaccinated to help protect immunocompromised children from vaccine-preventable infections.

The updated recommendations also broaden the focus on psychosocial evaluation. In addition to assessing medical eligibility, transplant teams should evaluate caregiver understanding, medication adherence, social support, developmental and neurocognitive status and barriers such as transportation, housing instability and financial hardship. They also should monitor for disparities in transplant access and promote living donor transplantation.

An important message for clinicians is to refer children for transplant evaluation earlier rather than later. Referral is recommended once complications such as growth failure, recurrent cholangitis, severe pruritus, portal hypertension, hepatic encephalopathy, or uncorrectable coagulopathy develop. The authors note that early evaluation gives transplant teams time to optimize nutrition, coordinate care and complete the assessment before irreversible disease progression occurs.

The guidance also emphasizes rapid evaluation of children with acute liver failure. Every child should be referred immediately to a pediatric liver transplant center, with transplant programs prepared to accept urgent transfers. Early genome or exome sequencing is also recommended for unexplained cases because it identifies an underlying diagnosis in about 37% to 50% of patients and can help inform transplant decisions.

The guidance also expands disease-specific recommendations for pediatric liver transplantation. Among the updates are earlier transplantation for selected inherited metabolic disorders, earlier evaluation of unresectable hepatoblastoma and transplantation for autoimmune hepatitis or primary sclerosing cholangitis when

"For children with acute liver failure, the message is simple: refer immediately to a pediatric liver transplant center."

complications persist despite treatment. Additional recommendations address cholestatic disorders, Wilson disease, intestinal failure-associated liver disease, metabolic dysfunction-associated steatotic liver disease, Budd-Chiari syndrome and liver retransplantation.

The guidance also includes several recommendations aimed at improving fairness in organ allocation. It recommends using updated Pediatric End-Stage Liver Disease-Creatinine and Model for End-Stage Liver Disease 3.0 scores for initial prioritization while preserving exception pathways for children whose clinical condition is more severe than their scores indicate. It also encourages wider use of living donor, split-liver and reduced-size grafts and supports future allocation policies that prioritize children for donor livers suitable for splitting.

According to Dr. Ng, one of the greatest challenges in developing the guideline was balancing the available evidence with the realities of clinical practice. "Many of the most important decisions in pediatric transplantation involve complex, individualized situations where high-quality pediatric data remain limited," she said.

She and her coauthors based the guideline on a systematic review of the literature published between 2016 and early 2025. The investigators screened 881 studies, reviewed 422 full-text articles, extracted data from 298 studies and ultimately based the recommendations on evidence from 178 studies.

"If there is one message I hope readers take away, it is that transplant evaluation is not simply about determining eligibility for transplantation," Dr. Ng said. "It is about understanding each child's unique needs and bringing together the expertise, resources and partnership required to help every child achieve the best surgical, medical and psychosocial outcomes, whether that ultimately involves transplantation or not."

The guideline was funded by the American Association for the Study of Liver Diseases. Several of Dr. Ng's coauthors reported research funding, consulting, advisory board participation, or honoraria from Mirum, Albireo, Gilead, Ipsen, Takeda, Merck, Viracor-Eurofins, Bridge to Life and other companies.

AGA update sets limits on Barrett's surveillance in older adults

"It may very well be reasonable to stop Barrett's surveillance or at least give patients the option to stop."

By Doug Brunk

Older patients with Barrett's esophagus or a history of colorectal neoplasia should not automatically continue endoscopic surveillance, according to a new AGA clinical practice update, which advises weighing overall health, life expectancy, ability to undergo treatment, and patient preference. Published in *Clinical Gastroenterology and Hepatology*, the expert review provides nine best practice recommendations on when to continue or stop surveillance.

"The US population is aging, and with the numerous GI conditions for which people are under endoscopic surveillance, timing was right to evaluate our current state of practice and think about if, when, and how to stop surveillance based on balance of benefits/harms," first author Audrey H. Calderwood, MD, MS, FACG, FASGE, professor of medicine at the Geisel School of Medicine and the Dartmouth Institute, Lebanon, New Hampshire, told *GI & Hepatology News*.

For physicians, the key is to consider a patient's overall health and likely life expectancy, rather than age alone. Most cancer screening guidelines recommend routine screening through age 75, individualized decisions from ages 75 to 85, and stopping after 85, the authors noted. Dr. Calderwood and colleagues noted that patients generally need a life expectancy of at least 10 years to gain a survival benefit from cancer screening. Prognostic tools that account for age, frailty, physical function, and other health conditions can help guide these decisions.

Key points from the update include: For patients with Barrett's esophagus, decisions about continued surveillance should consider other health conditions, life expectancy, procedure risks and patient preferences. About 90% of patients with Barrett's esophagus do not have dysplasia, and their risk of developing esophageal adenocarcinoma is about 0.1%-0.3% each year. In one study of patients successfully treated for Barrett's-related neoplasia, the risk of dying from other causes was 40 times higher than the risk of dying from esophageal adenocarcinoma. A cost-effectiveness analysis suggested that the best age to stop surveillance may range from 69 years for women with severe

comorbidities to 81 years for men without comorbidities.

Surveillance should stop at any age if a patient would not be able to undergo endoscopic therapy, surgery or cancer treatment if neoplasia were found. A life expectancy of less than five years and multiple health conditions may also support stopping surveillance.

For colorectal cancer screening after age 75, physicians should weigh the potential benefits against the risks of colonoscopy. Among patients ages 76-85 who underwent screening, colorectal cancer was found in only about 0.2%-0.5%, while advanced adenomas were found in 6%-8%. Colonoscopy caused an estimated 14-28 complications per 1,000 older patients. Overall, the update estimated about 26 complications per 1,000 colonoscopies, compared with colorectal cancer found in only two to three patients per 1,000.

Polyp history can also help guide decisions. Among patients older than 75 with low-risk adenomas, the risk of developing colorectal cancer within five years was about 0.5%. For those with advanced adenomas on their most recent colonoscopy, the five-year risk was 0.8%. By comparison, the risk of dying from causes other than colorectal cancer was about 22% within five years and 48% within 10 years.

The authors recommend that physicians document discussions with patients about the benefits and risks of colonoscopy and avoid routinely scheduling colonoscopy without a consultation after age 75. However, evidence on the best ways to stop surveillance is limited, and more long-term research is needed on outcomes after repeated colonoscopies.

Koushik K. Das, MD, reported consulting for Olympus. Gary W. Falk, MD, MS, reported consulting relationships with Adare/Ellodi, Bristol Myers Squibb, EsoCap, Exact Sciences, CDx, Castle Bioscience, Uniquity, Regeneron/Sanofi, Takeda, Upstream Bio, and Lucid, and equity in Merck, Bristol Myers Squibb, Pfizer, and AbbVie. The other authors reported no conflicts.

Dr. Calderwood spoke with *GI & Hepatology News* about what the guidance means for clinical practice.

Which life expectancy or frailty tool do you recommend physicians use routinely when deciding whether to stop surveillance?

Dr. Calderwood: I really like ePrognosis because it is easily accessible online and only takes a minute to input readily available data on the patient to get an estimate on life expectancy at 5, 10, and 14 years for ambulatory older adults. Super helpful!

How should the recent negative randomized trial influence Barrett's esophagus surveillance in otherwise healthy adults over 75?

Dr. Calderwood: The Barrett's Oesophagus Surveillance Versus Endoscopy at Need Study (BOSS) showed no differences in overall survival, cancer-specific survival, time to diagnosis of esophageal adenocarcinoma or cancer stage with every 2-year surveillance endoscopy vs. endoscopy for symptoms only in patients with Barrett's esophagus. As we note in the clinical practice update, the study did have some limitations including inclusion of patients without intestinal metaplasia (~25% of the cohort) and higher frequency of endoscopy in the surveillance group than suggested by current guidelines, leading the 2025 AGA clinical practice guideline on Barrett's esophagus to still recommend performing endoscopic surveillance over no surveillance. However, I do think the absence of benefit of surveillance here is useful when thinking about management of surveillance in adults 75 and older where competing mortality is increased. For patients age 75 and older without any esophageal dysplasia or in those with short-segment disease, it may very well be reasonable to stop Barrett's surveillance or at least give patients the option to stop.

For adults over 75 with prior advanced adenomas, when would you continue surveillance colonoscopy versus discontinue it or consider FIT?

Dr. Calderwood: I would continue surveillance colonoscopy if their life expectancy is greater than 10 years and the advanced adenoma was on their most recent colonoscopy or if their most recent colonoscopy was not high quality (meaning adequate bowel prep and complete to the cecum with long enough withdrawal time).

For adults 75 and older with prior advanced adenomas, I would discontinue surveillance colonoscopy if their most recent colonoscopy was high quality, their life expectancy is less than 10 years and the advanced adenoma was in the distant past or if the patient has difficulty with colonoscopy, is not interested in surveillance or has other priorities to tend to.

There isn't much data regarding FIT for use of surveillance in patients with recent advanced adenomas though I suspect more data will be forthcoming in the future. I would consider use of FIT in patients over 75 with non-advanced adenomas who are interested in surveillance and able to undergo and tolerate colonoscopy but who would prefer an alternate surveillance method (provided they would still be willing to have a colonoscopy if the FIT is positive). My team is conducting a RCT for older adults age 65-82 with recent low risk polyps comparing annual FIT vs. one time colonoscopy and hope to provide information on effectiveness and patient reported outcomes once the trial concludes.

Audrey H. Calderwood, MD
MS, FACG, FASGE



Panel proposes new criteria for acute severe UC

“They ‘look’ less sick, but they are actually much sicker than the patients with ASUC in 1955,” said senior author Peter D.R. Higgins, MD, PhD, MSc.

By Doug Brunk

Experts have proposed updated diagnostic criteria for acute severe ulcerative colitis (ASUC) that reflect today’s treatment landscape, replacing reliance on the 1955 Truelove and Witts criteria with a broader assessment of symptoms, laboratory findings, and endoscopic findings. The new recommendations are intended to help physicians identify severe disease in patients already receiving corticosteroids or advanced therapies, whose illness may be missed by the traditional criteria.

The recommendations were developed by an international panel of inflammatory bowel disease (IBD) experts and published in *Clinical Gastroenterology and Hepatology*. The group reached consensus through a four-round modified Delphi process involving specialists from Europe, North America, and the Asia-Pacific region.

ASUC is a life-threatening flare of ulcerative colitis that often requires hospitalization and prompt treatment. Delayed diagnosis can increase the risk for toxic megacolon, colectomy, and death. Although the Truelove and Witts criteria have been the standard for 71 years, they may not fully reflect how modern therapies alter the clinical presentation of severe disease.

Senior author Peter D.R. Higgins, MD, PhD, MSc, director of the IBD program in the department of medicine at the University of Michigan, Ann Arbor, explained why updated criteria are needed.

“The old criteria were from before we routinely used steroids and advanced therapies,” Dr. Higgins told *GI & Hepatology News*. “Most of our patients admitted for ASUC now are on both steroids and an advanced therapy (e.g. prednisone 40 mg and an infliximab infusion last week) — so they ‘look’ less

sick, but they are actually much sicker than the patients with ASUC in 1955, when Truelove and Witts criteria were developed.”

To update the criteria, the investigators assembled a panel of 12 internationally recognized gastroenterologists between April 2024 and September 2025. Using a four-round modified Delphi process, the experts evaluated 164 statements on symptoms, laboratory tests, endoscopic findings, imaging, and diagnostic pathways. Three co-chairs guided the discussions but did not vote, and agreement required support from at least 70% of the panel. A virtual meeting after the third round helped refine the proposed criteria before the final vote.

The panel agreed that updated diagnostic criteria are needed because the current framework no longer reflects modern clinical practice. Ninety-two percent of experts supported replacing or supplementing the existing criteria. They also agreed that diagnosis should be based on a combination of required “major” criteria and supporting “minor” criteria, which strengthen the diagnosis but are not sufficient on their own.

For patients already receiving advanced therapy or low-dose corticosteroids as outpatients, the panel recommended diagnosing ASUC when at least two of three major criteria are present along with at least two minor criteria. The major criteria are a C-reactive protein (CRP) level at least twice the upper limit of normal, six or more bowel movements in 24 hours, and visible blood in at least half of bowel movements over 24 hours. Minor criteria include low albumin, tachycardia, nocturnal bowel movements, anemia, fever, and an elevated white blood cell count. The

panel emphasized that even all three major criteria are not enough on their own without supporting minor findings.

The recommendations are different for patients already taking high-dose corticosteroids before hospitalization because these drugs can reduce inflammation and mask the severity of disease. For these patients, the panel recommended lower diagnostic thresholds. All three major criteria alone are considered sufficient, using a CRP level at or above the upper limit of normal instead of twice the upper limit, and visible blood in at least one-third rather than one-half of bowel movements. Alternatively, the diagnosis can be made when two major criteria are present along with at least two minor criteria.

The panel did not reach consensus on diagnostic criteria for patients who had not yet received treatment. The approach with the most support combined an elevated CRP level with either frequent bowel movements or visible bleeding, plus at least two minor criteria, but only 64% of experts agreed, short of the 70% threshold for consensus. The investigators said previously untreated patients are a more diverse group and often need additional testing to rule out infectious colitis and other conditions before ASUC can be confirmed.

AbbVie funded the study. Dr. Higgins and many coauthors reported consulting, speaking, research, or advisory relationships with multiple pharmaceutical companies.

GI & Hepatology News invited Dr. Higgins to elaborate on the recommendations.

How do you expect these new criteria to change the evaluation of patients who present with suspected ASUC after already receiving outpatient corticosteroids or advanced therapy?

Dr. Higgins: We should take into account the therapies that people’s UC has essentially blown through, and at least mentally account for the 40 mg prednisone and 700 mg of Remicade [infliximab] they got last week. This is still ASUC even though they are only having 4 bloody bowel movements.

What do you see as the biggest challenges to implementing these proposed criteria in routine clinical practice, particularly in community hospitals or centers with limited access to urgent endoscopy?

Dr. Higgins: The Truelove and Witts criteria have been around and taught for decades. And it is hard to unlearn things.

Because the panel did not reach consensus on diagnostic criteria for untreated patients, how should physicians approach these patients while awaiting prospective validation of the new criteria?

Dr. Higgins: For truly untreated patients (pretty uncommon in 2026), the old criteria should still work.

Is there anything else you’d like to say about this work?

Dr. Higgins: We need to recognize that ASUC today (after failing multiple therapies) is much less likely to respond to IV steroid monotherapy than the patients of 1955, or even 2005.

We need to recognize these refractory patients and consider using advanced therapy (with intravenous corticosteroids as co-therapy) as first line agents when hospitalized.

This can be complicated, as it adds costs to the hospitalization that may not be covered by the diagnosis-related group payment, especially for expensive on-patient drugs.

“High-dose corticosteroids can mask disease severity, prompting experts to recommend lower diagnostic thresholds for these patients.”

UK guideline opens a no-biopsy path to celiac diagnosis

Symptomatic adults in secondary care with tissue transglutaminase levels at least 10 times the upper limit of normal may forgo duodenal biopsy, but not patients seen in primary care.

By Doug Brunk

Selected symptomatic adults may now be diagnosed with celiac disease without undergoing duodenal biopsy, according to updated British Society of Gastroenterology guidelines that also revise recommendations for testing, biopsy collection, gluten challenge, and follow-up.

The optional no-biopsy pathway applies to symptomatic adults assessed in secondary care whose immunoglobulin A tissue transglutaminase (IgA-tTG) level is at least 10 times the assay's upper limit of normal. The decision should follow a discussion with the patient, and endoscopy remains appropriate for patients with red-flag symptoms, suspected alternative disease or another reason for upper GI evaluation.

The guideline, which includes 15 recommendations and 19 good practice statements, was published in *Gut*. It cautions that the no-biopsy approach should not be extended routinely to primary care, screening populations, or asymptomatic patients because its predictive accuracy may decline where celiac disease prevalence is low. Labs should use assay-specific thresholds and participate in quality assurance.

Some patients may still prefer histologic confirmation before committing to a lifelong gluten-free diet, first author Hugo A. Penny, MBBS, MRCP, PhD, of Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom, and colleagues noted. Biopsy also identifies potential celiac disease and seronegative disease, which a serology-only pathway may miss. Other key points from the guideline include:

- IgG-based serology and upper GI endoscopy with duodenal biopsies.
- Patients must continue eating gluten before testing because both serology and histology depend on an immune response to gluten. Those who have already eliminated gluten should undergo a gluten challenge of 3 to 6 grams daily for at least six weeks, with a lower dose and longer duration if needed.
- When biopsy is required, endoscopists should obtain at least four specimens from the second portion of the duodenum and two from the bulb, preferably in separate containers, because adequate sampling improves diagnostic yield.
- Diagnosis may be established when positive serology is accompanied by increased intraepithelial lymphocytes and crypt hyperplasia, with or without villous atrophy. HLA typing should generally be reserved for selected cases, primarily to exclude celiac

disease because the absence of HLA-DQ2 or HLA-DQ8 makes the diagnosis highly unlikely.

The guideline also broadens case finding. Physicians should test patients with persistent unexplained GI symptoms, weight loss, prolonged fatigue, severe mouth ulcers or unexplained iron, folate or vitamin B12 deficiency, and consider testing in those with unexplained neurologic symptoms, elevated liver enzymes, low bone density, subfertility or recurrent miscarriage. High-risk groups include first-degree relatives and patients with type 1 diabetes, autoimmune thyroid disease, inflammatory bowel disease and microscopic colitis.

A lifelong gluten-free diet remains the only accepted treatment, but the guideline places greater emphasis on specialist dietitian involvement and nutritional quality. Newly diagnosed patients should be referred to a dietitian with celiac expertise and connected with a reliable patient organization. Gluten-free oats may be introduced at the start of treatment if certified gluten-free and accompanied by clinical follow-up.

The authors emphasize that no single measure reliably assesses dietary adherence. They recommend combining dietitian assessment, symptom review, dietary tools and serology because normal tTG levels do not confirm strict gluten avoidance or mucosal healing.

All patients should receive regular follow-up for up to two years after diagnosis to assess symptoms, dietary adherence and nutritional status. Clinically stable patients may then transition to patient-initiated follow-up, while those with persistent symptoms, poor adherence or complications should continue structured care. Repeat biopsy is not mandatory for every asymptomatic patient but should be considered when planning long-term management because histology remains the only reliable way to assess mucosal healing.

Persistent symptoms warrant systematic reassessment because ongoing gluten exposure is the most common cause, although disorders of gut-brain interaction, microscopic colitis, inflammatory bowel disease and slow mucosal healing should also be considered. Patients with suspected refractory celiac disease should be referred to specialist centers. Open-capsule budesonide is recommended as first-line treatment for type 1 refractory disease.

For practicing physicians, the guidance supports fewer biopsies in a carefully selected minority while emphasizing rigorous diagnostic standards, adequate biopsy sampling, and structured follow-up for all other patients.

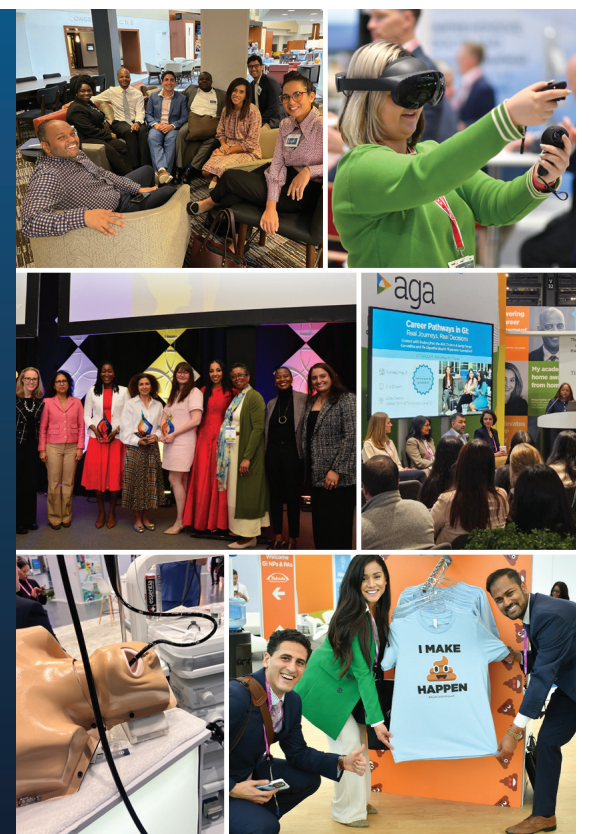
Dr. Penny and several coauthors reported honoraria, consulting or advisory roles, research funding, grants, patents, or other support from pharmaceutical, biotechnology and diagnostic companies. Some also reported roles with Coeliac UK.

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A framework for ethical and legal social media use among gastroenterologists

By Keshav Desibhatla; Supriya Rao, MD; Jennifer Fijor, MSN, RN, FNP-BC; and Wendi LeBrett, MD

Introduction

Millions of patients consume social media content about health care daily. Nearly 80% of Americans search social media for health information.¹ Whether accurate or not, social media serves as a major source of information influencing health decisions. As health professionals, it is our responsibility to understand, educate, and provide evidence-based information for patients where they are actively seeking information. Most health information created online is by individuals without professional expertise.² As clinicians engage in social media, they must ensure patient privacy, professionalism, transparency, and information integrity. Prior guidance for gastroenterologists has addressed these issues,³ but newer information-sharing platforms, such as TikTok, Instagram, and YouTube, necessitate updated information that reflects their unique characteristics. Rather than discouraging clinicians, this article aims to provide a timely legal and ethical framework for clinicians to implement before engaging in social media content creation.

Patient privacy

Although the Health Insurance Portability and Accountability Act (HIPAA) predates social media, the U.S. Department of Health and Human Services has repeatedly affirmed its protection of patient privacy. The revised Privacy Rule, a subsection of HIPAA, indicates all individually identifiable health information known as protected health information (PHI) must be protected, including online.⁴ Exposure of PHI on social media is a serious violation of these regulations. The most common pitfalls fall into four distinct categories.

1. In medical education, composite cases are useful for teaching, but if too specific, rare demographics and distinctive timelines can identify a patient despite the omission of names.
2. Videos taken in a clinical setting can inadvertently capture PHI or individuals such as patients without their consent.
3. Social media direct messages between clinicians and users can become a liability once clinical specifics are disclosed. Despite the seemingly private conversation space, the exchange becomes a documented record, lacks the security to protect PHI, and introduces medicolegal risk.
4. Comment sections on social media posts often include self-disclosed PHI. Clinicians should be careful not to confirm or expand on such comments.

To avoid potential HIPAA violations, clinicians should employ practical guardrails. For case composites, consider following the “two-patient

rule” to reduce the risk of identification. Some clinicians on social media include de-identified patient images for teaching purposes on social media, but this practice should be exercised with caution and ensure patient consent. A safer practice clinicians should consider is to limit images to what is already publicly available. Finally, clinicians can employ automated messaging on social media platforms to direct users toward individualized medical evaluation instead of general online advice. The American Medical Association’s social media use guidelines emphasize that any content published on the internet is permanent and thus should be approached as an ongoing professional responsibility to protect patient privacy.⁵

Clinician-patient relationship

There exists a legal gray zone between providing information online and giving medical advice. At what point does a clinician providing information online evolve into medical advice? Unfortunately, there is no uniform answer. Although the general idea is that personalized medical care should not be discussed online, there is much state-by-state variability in what constitutes establishing a clinician-patient relationship. While some states require explicit consent, others are more context-dependent and driven by what a reasonable patient deems important.⁶ The closest analogy to navigating these boundaries is telemedicine. A clinician is typically required to hold licensure in the patient’s state for any synchronous clinical exchange. However, social media content reaches a national audience of 50 states simultaneously. Standardized rules do not yet exist for social media education. Whether licensure requirements should extend to social platforms remains an active debate, especially if a patient in another state is harmed based on information from social media.⁷

Another sensitive area of clinician-patient relationships includes online reviews or complaints. While it may be tempting to respond, a patient posting their own medical information does not waive their HIPAA rights. If a clinician confirms these details in a response, this exchange becomes evidence in litigation and a potential HIPAA violation. Disclaimers such as “not medical advice” may help but are not dispositive. Instead, clinicians are advised to direct followers to seek individualized medical care and avoid personalized comments. Malpractice policies do not commonly cover social media activity by default. Limited liability companies may offer some protection, but regardless, clinicians should consult their employer’s specific policies before posting. Some companies explicitly forbid employees from posting on social media, while others claim copyright or ownership of any content created by clinicians under their employment.

Brand partnerships

Clinicians are among the most trusted voices on social media and brands are eager to partner with clinicians to create promotional content. Producing sponsored content in exchange for financial compensation can be polarizing and is



heavily scrutinized by regulatory agencies such as the Federal Trade Commission (FTC). Additionally, clinicians on social media risk loss of trust among followers by engaging in financial relationships in exchange for sponsored content. Some clinicians explicitly choose not to engage in external partnerships or mention specific brands in their non-sponsored (organic) content.

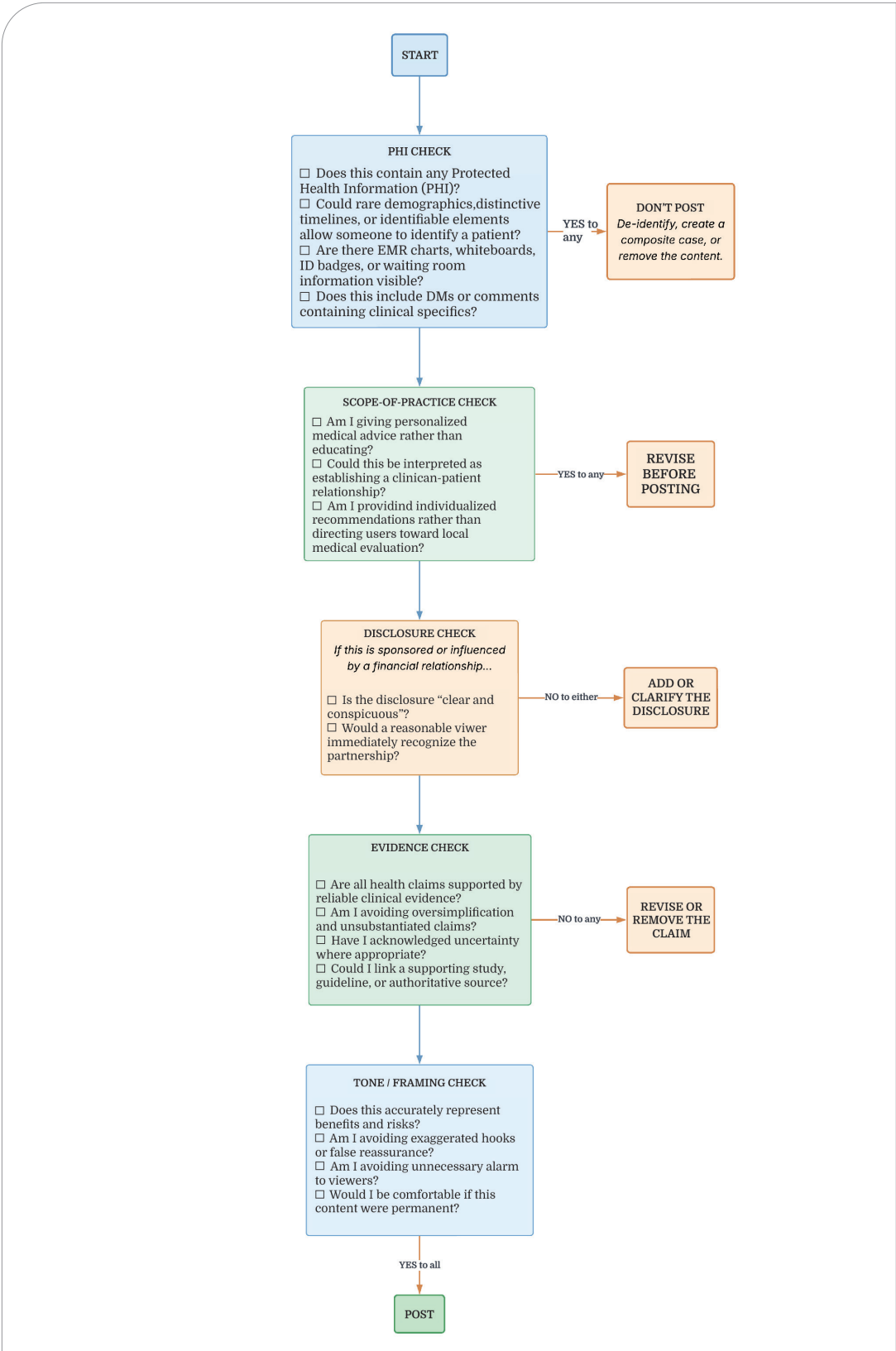
Nevertheless, many prominent clinicians on social media do engage in brand partnerships and tend to follow similar practices. First, exercise high selectivity regarding companies or products to endorse, as any content sponsored or unsponsored reflects professional judgment and integrity. Second, adhere to FTC guidelines to ensure transparency and accuracy.⁸ Clinicians are required to disclose any relationship that might affect how the audience weighs the endorsement. Moreover, the disclosure must be “clear and conspicuous,” a standard the FTC now defines as difficult to miss and, on social media, effectively unavoidable.

Moreover, liability through external partnerships is personal and extends in multiple directions. Clinicians should not assume that a brand or agency partner will manage disclosures on their behalf. Violations include civil penalties, and recent enforcement activity has focused specifically on health professionals promoting products without adequate disclosure. Compliance with the FTC is necessary but not sufficient, as Food and Drug Administration guidelines, the Physician Payments Sunshine Act, state medical board regulations, specialty-society guidance, or employer-specific regulations may impose overlapping obligations.

Finally, brand partnerships should be managed with the same formality as any other business arrangement. This entails a legal contract rather than relying on informal correspondence. A well-drafted agreement should address the deliverables of the partnership, the compensation structure, the duration, and any exclusivity provisions that might restrict the clinician from working with competing brands. Attention should be paid to intellectual property and content ownership, as many standard agreements assign ownership or broad usage licenses to the sponsoring company. Failure to do so potentially allows brands to repurpose a clinician’s likeness, name, or statements in future advertising. Protections that preserve editorial control and limit how a brand may use their identity are not merely legal formalities but protect a clinician’s professional reputation.

Misinformation and algorithms

Social media algorithms reward engagement, such as user retention and shares rather than content verifiability.⁹ A cross-sectional analysis of gastroenterology content on TikTok identified health misinformation as common and evidence-



A practical pre-post checklist

based treatments as underrepresented.¹⁰ The medical ethics principle to “do no harm” extends beyond the clinic and into social media. Content creators should be careful to avoid oversimplification. Hooks can backfire if they sacrifice clinical nuance for bold claims such as a single food that can “cure bloating.” These claims overstate a treatment’s benefit and generate false reassurance. Similarly, overemphasizing rare complications can produce undue alarm and erode trust. The optimal presentation of medical information is grounded in evidence-based care and transparent about multifaceted outcomes. By referencing studies in the caption or

acknowledging uncertainty in an emerging field, clinicians will build trust and reduce liability.¹¹ Social media rewards brevity and engagement, while medicine values nuance and uncertainty. One of the greatest ethical challenges for clinician creators is translating complex evidence into accessible language without oversimplifying the science. Responsible clinician creators should strive to make information understandable while acknowledging uncertainty when it exists. Artificial intelligence (AI) has become increasingly integrated into content creation. While AI may assist with drafting captions, organizing information, or editing language, clinicians remain responsible

for the accuracy, completeness, and clinical appropriateness of any information published.

Conclusion

Social media requires the same professional standards as any other clinician-patient relationship, just at greater visibility, scale, and speed. Online health information for patients in these spaces can be troubled by misinformation, whether by patients themselves or uncredentialed individuals. Clinicians are encouraged to engage appropriately and should feel prepared to navigate legal and ethical implications as outlined in this article. Content creation represents additional work, and clinicians should establish practices that prevent consistent digital engagement from contributing to burnout. As the reach and influence of digital platforms continue to grow, clinicians must pursue ongoing education in engaging responsibly across social media — including peer-reviewed publications, conferences, and other educational forums — to ensure that medical information reaching the public is accurate, ethical, and evidence-based.

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Meet your new editor in chief

Dr. Berkeley Limketkai brings an engineer's eye and a methodologist's rigor to *GI & Hepatology News*.

Berkeley N. Limketkai, MD, PhD, has spent his career where IBD, nutrition, and clinical informatics meet. Now he takes the helm as editor in chief of *GI & Hepatology News*, succeeding Megan Adams, MD, JD, MSc, who has led the newspaper since 2022. Clinical Professor of Medicine and Director of Clinical Research at the UCLA Center for Inflammatory Bowel Diseases, he trained at the University of Cincinnati and Johns Hopkins University and is board certified in gastroenterology, clinical informatics, and as a physician nutrition specialist.

In this month's Member Spotlight, he reflects on a childhood fascination with the gut, communicating uncertainty to patients, and separating hype from utility.

Congratulations on taking the helm! For readers who know your research but not your personal story, what do you most want them to know about you as you step into this role?

Dr. Limketkai: Thank you! I am deeply grateful to AGA for providing me with this incredible opportunity to help guide *GI & Hepatology News* into its next chapter of growth. Dr. Megan Adams, the former editor in chief, has done an outstanding job, and she leaves very large shoes to fill.

There is much I could share, but I will focus on two aspects of my personality that most strongly define my *raison d'être* at work — besides, of course, the need to financially survive.

First, after much introspection, I have come to realize that a core characteristic of my leadership and work styles is helping others succeed, even when doing so occasionally comes at a personal cost. I regularly invest long nights and weekends mentoring trainees as they pave their paths into the future. Trainees inevitably move on, but I know that my involvement can make a meaningful impact at a pivotal point in their lives. Similarly, in research, I have helped many colleagues build their research portfolios, often while serving as a hidden engine or supporter. These efforts may draw precious time and energy away from my own research program, but I have learned that helping others grow and enjoying the journey along the way matter more to me than accolades.

Second, my passion for work is driven by the synergy between clinical care and research. In clinic, thought-provoking questions asked by patients and the knowledge gaps exposed in ever-imperfect but always-improving clinical care generate research questions and hypotheses that fuel my research. Through clinical research, I then seek answers to these questions and investigate novel approaches to improving care and, ultimately, the lives of our patients. In turn, I integrate research evidence — be it from my own work or that of others — when providing clinical recommendations, counseling patients, and sharing hope for a better future.

I feel blessed to be afforded these opportunities, and if funding were not an issue, I could imagine continuing this until the day I hang up my white coat for good.

Your career uniquely spans IBD, nutrition, and a pre-medical background as an internet startup developer. What originally drew you to gastroenterology, and how does that tech-and-data mindset shape how you look at medical news today?

Dr. Limketkai: In hindsight, I wonder whether my fascination with the digestive system has lingered since childhood. In grade school, when assigned to create a poster of an organ system, I



“In clinic, thought-provoking questions asked by patients and the knowledge gaps exposed in ever-imperfect but always-improving clinical care generate research questions and hypotheses that fuel my research.”

vividly remember choosing to illustrate the digestive tract. I was captivated by the digestive process and its ability to break down food into its molecular constituents that are then used to sustain all other bodily functions. Then again, perhaps this was simply the typical childhood fascination with poop.

Nonetheless, my interest in digestion and medicine did not become apparent to me until later in life. My early career aspiration was to become an aerospace engineer, although I was advised against pursuing that path amid the downturn in aerospace spending after the Cold War. Given my engineering mindset, I joined an internet startup after college, and following the dotcom bust, I pivoted to biotech and later to medicine, where my long-dormant interest in the digestive tract and nutrition resurfaced.

As digital technology and artificial intelligence surge across every industry, technological fluency becomes increasingly important. Healthcare often lags behind other sectors in adopting cutting-edge technologies, but change is inevitable. My background in technology and medicine, along with my board certification in clinical informatics, makes me particularly attentive to advances in technology and its integration into healthcare. I am also naturally curious about how things work under the hood and how they can be applied in practice.

Your research often connects nutrition and IBD, an area patients care deeply about but where clinical evidence can be hard to translate. What has that work taught you about communicating scientific uncertainty to both clinicians and patients?

Dr. Limketkai: As a methodologist for clinical guidelines and systematic reviews, I frequently have to contend with heterogeneous and imperfect data, assess the quality of research evidence, and synthesize core conclusions. For example, in the context of dietary interventions for IBD, the formally graded quality of evidence is low or very low. At the same time, as a clinician, I cannot allow a paucity of data to paralyze me from providing practical guidance to patients. I recognize that a lack of data does not necessarily signify lack of effect; in many cases, the rigorous studies needed to answer these questions have just not yet been done. To navigate this tension, I typically communicate such information to my audience with four components in mind: the theoretical or biologic basis, the level of evidence, the practical effects observed, and the potential risks.

When speaking with clinical colleagues, I tend to place slightly greater emphasis on the underlying science and strength of evidence. When speaking with patients, I focus more on expected practical benefit and risk, while still explaining the rationale and quality of evidence so they have appropriate context for shared decision-making.

You've noted that clinical care and research should strengthen each other. In your opinion, how can *GI & Hepatology News* help busy clinicians seamlessly translate emerging evidence into daily practice?

Dr. Limketkai: These are exciting times. Research and practice-changing discoveries are rapidly advancing. For busy clinicians, a key challenge is identifying which studies are most relevant and worth reviewing. Not every breakthrough finding translates into meaningful change at the bedside, and research findings may sometimes appear to contradict each other, leading to a natural uncertainty on how to best interpret the data and apply them in practice.

For these reasons, I view *GI & Hepatology News* as an invaluable source of carefully curated, high-yield, practice-relevant information for busy clinicians. The newspaper also interviews experts who provide important context for new research findings and help explain their practical implications. Even when emerging data or news do not immediately lead to actionable change, the information shared can still offer clinicians a valuable glimpse into what may lie ahead.

You've worked in academia, the VA, and multidisciplinary programs. How has navigating those different clinical environments shaped your understanding of what practicing gastroenterologists need from a news source?

Dr. Limketkai: This diversity of experiences has deepened my appreciation for the similarities and differences across practice environments. Working primarily in academia has also allowed me to collaborate closely with gastroenterology fellows, who bring a wide range of interests, perspectives, and career aspirations. Through these interactions, I have gained insight into the broad spectrum of educational needs, knowledge gaps, and priorities within gastroenterology.

In addition, a universal challenge among practicing gastroenterologists is the pressure of very busy schedules and the need for efficient mechanisms to access relevant, high-quality information.

With areas like AI and microbiome science moving incredibly fast, medical headlines can easily outpace rigorous evidence. What is your framework for separating clinical "hype" from true utility?

Dr. Limketkai: Precisely because these advances are so exciting, it is understandably easy to be swept away by unbridled enthusiasm

("hype") before fully assessing the feasibility and practicality of new discoveries. I do not view this as a fault. Rather, it is often a necessary quality of visionaries who pave the way for future innovation, even when feasibility or application is not yet clear. If not for the courage to dream, we would not yet have artificial intelligence as we know it today.

Nonetheless, when reporting new developments to busy clinicians, we must discern what is possible now versus what may be possible twenty years from now. To distinguish hype from true utility, I evaluate research data through several lenses: strength of evidence, feasibility of translation or deployment, and practical significance in the current era. Even when a groundbreaking technology emerges, logistical considerations (e.g., infrastructure, cost, regulation, scalability) must be weighed. Clinical relevance is equally important. For example, an innovative widget that automatically counts the number of nostril hairs in a rodent might be scientifically impressive, but would it be practical for a gastroenterologist? Likely not. By contrast, an AI agent capable of reviewing reams of medical charts and prepopulating previsit notes could be immensely helpful.

You'll be collaborating with AGA, Conexiant, and your board of associate editors. What kind of collaborative culture do you want to build, and what diverse perspectives are you most eager to bring to the table?

Dr. Limketkai: I am a firm believer in team science. I value the ways in which a rich diversity of ideas, opinions, and perspectives can lead to a better final product than any one person can develop alone. I also recognize that the knowledge, experiences, and skills that others bring to the table complement — and often compensate for — my own limitations. With this in mind, the incoming board of associate editors has been carefully selected to include renowned clinicians from diverse backgrounds, subspecialty interests, practice settings, and geographic representation.

Through this collaboration among AGA, Conexiant, and the board of editors, we hope to create a working culture in which everyone's input is valued, including that of our readers! Of note, "valued" does not mean that every suggestion will necessarily be implemented; instead, it means that all feedback will receive thoughtful consideration. Even as we have associate editors assigned to specific sections — such as Dr. Alyssa Parian with *The New Gastroenterologist* and Dr. Leila Neshatian with *Perspectives* — we will promote a culture in which everyone is encouraged to share ideas and suggestions.

I have also asked Drs. Brian Kim and Marc Piper to assist with *The New Gastroenterologist*, given their deep involvement in fellowship education. Our hope as a team is to foster a collaborative culture that is professionally fulfilling, enjoyable, and respectful, all while producing a publication that addresses the news needs and interests of practicing gastroenterologists and hepatologists.

A year from now, what do you hope readers say has evolved about *GI & Hepatology News*, and what do you hope they feel remained rock-solid?

Dr. Limketkai: I hope *GI & Hepatology News* continues to firmly maintain its position as a premier news source for practicing gastroenterologists and hepatologists, delivering a steady stream of high-yield, practice-relevant information. In the years ahead, I would be excited to see the publication expand its reach through a more robust online presence.

Just as science continues to evolve, so too does the way clinicians consume news and information. For busy clinicians, we will strive to provide timely, digestible content that can be accessed quickly and conveniently: while on the go, between patient visits, during lunch breaks. Anytime. Anywhere.

Lightning round

Who inspires you and why?

My parents are my role models for patient and selfless love, whom I strive to emulate.

What is your favorite GI organ and why?

Intestines: the centers of the digestive universe.

What is your favorite way to spend a day off?

Paying off massive sleep debt.

What is the most challenging case you worked on recently and what you learned from it?

Medication-refractory Crohn's disease with short bowel syndrome that was not amenable to further surgical intervention. Lesson learned: sometimes "healing" just means showing that you care.

Describe your dream retirement.

Traveling the world with my wife without having to think about my Epic In Basket.



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