# Bridge the GHAPP

Gastroenterology & Hepatology
Advanced Practice Providers

# NEWSLETTER

## VOLUME 10

# LETTER FROM THE COMMUNICATIONS COMMITTEE

**Dear Readers,**

It is unbelievable that summer is coming to an end, and we are rounding on the holidays once more.

This year has already held a lot of changes – within GHAPP, our committees have restructured and reformed to be more robust than ever before; within the liver community new medicines are emerging left and right; and within the greater GI community, guidelines and treatments have been revised and updated, enhancing the quality of are we can offer our patients.

We are looking forward to learning about implementing all of these changes and more, starting with our upcoming GHAPP National Conference, being held Sept 12 -14th in National Harbor, MD. We here at GHAPP feel humbled, grateful, and just stoked about the incredible turnout and growth that our meetings have had over the last seven years. It is because of you, our wonderful members, that we are here today.

As we think about the holidays coming, let us remember that first comes the celebration of us – the amazing gastroenterology and hepatology APPs that we are – that make us proud to be a part of GHAPP, the National Conference and key members of the specialties of Gastroenterology and Hepatology overall. I hope to see all of you at the conference and to be able to celebrate our accomplishments together again this year.

In Health,
Allysa Saggese, NP

## TABLE OF CONTENTS

# Promising Pills for PBC

Allysa D. Saggese, MSN, AGPCNP-BC

It's been an exciting year for liver disease and promising medications. For the first time in ten years, not just one, but TWO new medications for the treatment of Primary Biliary Cholangitis (PBC) have hit the market: Iqirvo (elafibranor) received FDA approval on June 10th of this year, and Livdelzi (seladelpar) received FDA approval on August 14th of this year. These approvals mark significant progress in expanding treatment options for PBC patients.

These two medications have similarities and differences, which I will outline here:

Similarities:

- Both are what we call PPARs (peroxisome proliferator-activated receptor) agonists.
- Both medications are indicated for PBC as second-line therapy in combination with ursodiol (UDCA) in adults with inadequate response to UDCA or as monotherapy in adult's intolerant of UDCA. Patients remain on UDCA while taking this medication if they are already on it.
- Both work on inhibiting bile acid synthesis and reducing inflammation in bile ducts.
- Both met their primary endpoint of reducing alkaline phosphatase level to < 1.67x upper limit of normal (ULN).
- Both are one pill, once a day, given with or without food.
- The most common side effect of both medicines is an upset stomach.
- Both carry a contraindication to use in those with biliary obstruction and decompensated liver disease.
- Both medications may have drug-drug interactions, so it is advised to check your patient's medication history before prescribing or starting either medication.
- Neither have been well studied or tested in pregnancy or lactation.
- There is a warning of the risk of bone fractures for both medications, and patients should be monitored with standard-of-care screenings for metabolic bone health.
- Both medications have the potential to cause liver test elevations, so close monitoring when starting a patient on either medication is encouraged.

## What is Primary Biliary Cholangitis (PBC)?

I'm here explaining how we're all excited about new medications that have hit the market for a rare liver disease – but wait, what is it exactly?

Primary Biliary Cholangitis (PBC) is a rare autoimmune liver disease that leads to progressive destruction of the bile ducts, resulting in liver damage and potentially cirrhosis if left untreated. The liver is made up of normal liver tissue and intrahepatic bile ducts that run through it. Bile ducts help make and transport bilirubin, a component of bile – a necessary excretion for digesting fats and fat-soluble vitamins, as well as what makes poop brown.

PBC used to be called Primary Biliary Cirrhosis as it was usually found and diagnosed in a patient only after they were found to have cirrhosis. This highlights the progressiveness of the disease if left untreated. Now, PBC is more easily diagnosed at an earlier stage of fibrosis or before fibrosis even has a chance to form. Diagnosis is made by presence of two out of three criteria: (1) an elevated alkaline phosphatase at least > 1.5 x the upper limit of normal (ULN), (2) a positive anti-mitochondrial antibody level, (3) evidence of PBC on liver biopsy. It cannot be seen on or diagnosed by imaging studies. This disease is more often found in women overall. Patients may also present with symptoms such as fatigue and itch, though some patients have no symptoms at all.

First-line treatment of PBC is ursodiol (UDCA) given at 13-15mg/kg, split into two or three daily doses. Second line therapies include Ocaliva 5mg or 10mg once a day, Iqirvo 80mg once a day, or LIvdelzi 10mg once a day, in addition to UDCA, or these can be used as monotherapy for patients in whom UDCA is not tolerated.

**Sources:**

AASLD. (2019). Primary biliary cholangitis: 2018 pracice guidance from the American association for the study of liver diseases. Retrieved from: https://journals.lww.com/hep/Fulltext/2019/01000/Primary_Biliary_Cholangitis__2018_Practice.32.aspx.

Pandit S, Samant H. Primary Biliary Cholangitis. [Updated 2023 Feb 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK459209/.

Differences:

- Iqirvo is a dual nonspecific PPAR alpha and beta/delta agonist, while Livdelzi is a highly selective PPAR delta agonist (aka “delpar”).
- Iqirvo is an 80mg tablet, Livdelzi is a 10mg capsule.
- In trials, a biochemical response rate was defined as alkaline phosphatase < 1.67x ULN. Iqirvo had a 51% response rate in subjects versus a 4% rate in placebo. Livdelzi had a 61.7% biochemical response rate versus a 20% rate in placebo.
- By the end of 1 year, Iqirvo induced normalization of alkaline phosphatase levels in 15% of subjects, and with Livdelzi, 25% of subjects normalized their alkaline phosphatase in trials.
- A response to Iqirvo occurred by Week 4 and was sustained through Week 52.
- In the Iqirvo trials, 35% of participants had F3-F4 fibrosis/cirrhosis; in Livdelzi trials, 14% had cirrhosis. Both trials excluded patients with decompensated liver disease.
- Both medications reported a decrease in reported pruritis, however Livdelzi specifically reduced itch by Month 1, reduced itch 2x more than in placebo and maintained a reduction in itch by Month 6 through Month 12.
- In addition to upset stomach, Iqirvo’s other potential side effects include diarrhea, nausea, and abdominal pain. Livdelzi other potential side effects include headache, abdominal pain, dizziness and abdominal distention.

With both medications on the market, we can expect further real-world use data to be collected in time and more data from the ongoing open-label trials for long-term safety and efficacy. Neither medication has yet proven long-term effects of preventing liver decompensation and the need for transplantation. However, the reduction or normalization of alkaline phosphatase levels is hopeful they will prove long-term outcomes of reducing overall mortality. These medications both had robust results to support their approvals, and everyone in the liver world is excited to be able to offer more second-line treatments to their patients with PBC.

**Sources:**

PI for Iqirvo

PI for Livedelzi

Crist, C. (Dec 2023). Elafibranor appears effective, safe for primary biliary cholangitis. Mescape. Retrieved from: https://www.medscape.com/viewarticle/elafibranor-appears-effective-safe-primary-biliary-2023a1000wud.

Brooks, M. (Aug 2024). FDA grants Livdelzi accelerated approval for primary biliary cholangitis. Medscape. Retrieved from: https://www.medscape.com/viewarticle/fda-grants-livdelzi-accelerated-approval-pbc-2024a1000ezf?ecd=WNL_clinicdgst_240821_MSCPPERSO_6766069_pos1&uac=308743FY&impID=6766069.

Hirschfield, G. et al. (Feb 2024). A phase 3 trial of seladelpar in primary biliary cholangitis. N Engl J Med. 390:9. P 783-794. Retrieved from: https://www.nejm.org/doi/10.1056/NEJMoa2312100?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

Genfit/Ipsen. (Nov 2023). Results from Ipsen’s ELATIVE pivotal phase iii trial of elafibranor in PNC presented as late breaking data at AASLD congress and published in New England Journal of Medicine. Retrieved from: https://ir.genfit.com/news-releases/news-release-details/genfit-results-ipsens-elativer-pivotal-phase-iii-trial; https://www.ipsen.com/us/press-releases/results-from-ipsens-elative-pivotal-phase-iii-trial-of-elafibranor-in-pbc-presented-as-late-breaking-data-at-aasld-congress-and-published-in-new-england-journal-of-medicine/.

Livdelzi Website: https://www.livdelzi.com/?gad_source=1&gclid=Cj0KCQjwlIG2BhC4ARIsADBgpVRXWU6OBEggZ7cseOvN8sJvNUWQMlRV8sQRvZgs6Bi9xHrlaGmfFrMaAh5CEALw_wcB&gclsrc=aw.ds.

Iqirvo Website: https://www.iqirvohcp.com/efficacy#biochemical-response.

# New Joint Guideline on Colonoscopy Quality Indicators

Sarah Enslin, PA-C

The American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) have released an updated joint guideline on quality indicators for colonoscopy.[1,2]

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States over >150,000 new cases annually and ~50,000 deaths.[3] This high mortality rate underscores the critical need for effective screening methods, as early detection can significantly improve survival rates. Colonoscopy is widely regarded as the gold standard for CRC screening because it allows for the early detection of both cancerous and precancerous lesions and facilitates the immediate removal of polyps during the procedure. This dual function of detection and prevention makes colonoscopy an essential tool in reducing CRC incidence and mortality. However, the quality of the exam can vary depending on several factors, such as endoscopist's training and experience, quality of bowel preparation, and variations in patient anatomy, which can affect the overall effectiveness of the screening.

The update guidelines, published in the September 2024 issues of *The American Journal of Gastroenterology* (AJG) and *Gastrointestinal Endoscopy* (GIE), provides comprehensive recommendations and quality metrics. Quality indicators are critical to the effectiveness of colonoscopy and help ensure that high standards are met consistently. The updated priority quality indicators include:

1. **Adenoma Detection Rate (ADR) – target ≥ 35%:** This metric measures how often endoscopists identify adenomas in the colorectum. A higher ADR is associated with a lower risk of post-colonoscopy colorectal cancer, making it a crucial measure of a colonoscopist's effectiveness in identifying potential cancer precursors. This was previously calculated for patients ≥ 50 years old undergoing their first screening colonoscopy. The updated recommendation is to include all patients ≥ 45 years old undergoing a colonoscopy for screening, surveillance or diagnostic evaluation, excluding previous positive non-invasive screening tests, patients with underlying high risk genetic cancer syndromes and those with inflammatory bowel disease.
2. **Sessile Serrated Lesion (SSL) Detection Rate – target ≥ 6%:** This indicator tracks the detection rate of sessile serrated lesions, implementing the same criteria as ADR. Detecting SSL lesions is vital for CRC prevention, as they can be more challenging to identify and are a significant contributor to cancer risk if missed.
3. **Rate of Using Recommended Screening and Surveillance Intervals – target ≥ 90%:** This quality indicator ensures that colonoscopies are scheduled at appropriate intervals based on individual patient risk factors and prior findings. Adhering to recommended intervals is essential for maximizing the efficacy of CRC screening and surveillance, thereby improving patient outcomes.
4. **Bowel Preparation Adequacy Rate – target ≥ 90%:** Adequate bowel preparation (Boston Bowel Preparation Score of ≥ 2 of all 3 colon segments) is essential for a thorough colonoscopy, as it ensures clear visibility of the mucosa and improves the accuracy of lesion detection. Data suggests split bowel prep is superior to one-day prep. Patients undergoing screening or surveillance colonoscopy with inadequate bowel prep should undergo a repeat examination within 1 year.
5. **Cecal Intubation Rate - target ≥ 95%:** This quality indicator ensures complete colonoscopy with full intubation of the cecum and photodocumentation of cecal landmarks. This remains a priority quality indicator in the update however it is acknowledged that most gastroenterologists achieve and maintain cecal intubation rates above target therefore continued measurement in optional once high performance has been documented.

Ultimately, these guidelines are designed to elevate the practice of colonoscopy to ensure that all patients receive the highest standard of care. By adhering to these updated recommendations, healthcare providers can significantly impact the early detection and prevention of colorectal cancer, thereby saving lives and improving the quality of healthcare delivery.

1. Rex D, Anderson J, Butterly L, et al. *The American Journal of Gastroenterology.* 2024:10.14309/ajg.0000000000002972, August 21, 2024. | DOI: 10.14309/ajg.0000000000002972.
2. Rex D, Anderson J, Butterly L, et al. *Gastrointestinal Endoscopy.* 2024; 100(3): 352-381, August 21, 2024. | DOI: 10.1016/j.gie.2024.04.2905.
3. https://seer.cancer.gov/statfacts/html/colorect.html.

# We are so excited for the 7th Annual GHAPP National Conference!

## Education Committee Members

Kimberly Orleck, Chair; Moriane Joseph, Co-chair; Erin Garris; Bridget Howard; Edith G. T. Johannes; Natalie Mul; Amy Rourke; Norma Solis; and Hilary Ugras

We listened to the feedback from last year's attendees and are excited to have increased our hepatology topics this year. In addition to the NEW inpatient hepatology summit, which will cover topics such as alcoholic hepatitis and hepatorenal syndrome, we will also offer a MASH boot camp, including updates on newly approved treatments for MASH and many hepatology workshop options.

In addition to some great new APP speakers, we also have new topics being presented this year, including cannabis-induced hyperemesis and medical management of weight loss, including GLP-1s and how these medications are impacting our patients but also our day-to-day clinic and endoscopy operations.

Treatment options and positioning strategies for IBD have evolved considerably since our last conference. Our IBD session will feature exciting talks such as "New Kids on The Block" on positioning strategies for Crohn's Disease and Ulcerative Colitis. These sessions aim to empower APPs to discuss all IBD therapies with confidence. For those new to GI, we are hosting an IBD boot camp on Thursday, which will provide a comprehensive disease state overview and treatment goals to prepare you for the subsequent IBD talks in the plenary and workshops.

For the inpatient APPs, we will cover inpatient hepatology topics as well as inpatient GI topics, including variceal bleeding, mesenteric colitis, mesenteric vein thrombosis, and more!

We are looking forward to learning with you!

## Membership Engagement Committee
### Shannon Todd PA-C, MHS, MPAS

Many exciting changes have occurred within our committee this year. Restructuring has combined the MEC with the Communications Committee into one large group with multiple subcommittees, thus providing more hands-on opportunities for members to contribute. Here is a list of our current committees and participants.

**Communications Division Chair: Alyssa Saggese**
Scholarships: Allysa Saggese
Social Media: Maileys Ortega, Andrea Keller, and Sharon Rimon
Newsletter: Alyssa Saggese, Sarah Enslin, and Alizabeth Van Wieren

**MEC Division Chair: Carol Antequera**
Mentorship: HoChong Gilles and Suzanne Robertazzi
Abstracts: Angelina Collins and Kristina Skarbinski
Awards: Monica Nandwani, Palak Patel, Alizabeth Van Wieren, Mikhail Alper, Suzanne Robertazzi, and Carol Antequera

Did you know we gave out 50 scholarships to the GHAPP National Conference at National Harbor this year? Our winners received free registration, along with hotel and airfare. They submitted applications, and some will be featured in the Member Spotlights in the future. Look for them by their badge tag, “Scholarship Recipient.”

Our social media subcommittee works to increase the engagement of our members on social media platforms, including posting about new clinical guidelines, topics from DDW, evidence-based medicine topics, etc. If you enjoy a particular lecture at the upcoming GHAPP National Conference- let someone know and post about it. **#GHAPP2024**

## FOLLOW US!


@GastroHepAPP


@GastroHepAPP


@gastrohepapp

**Exciting News!**

At the national meeting, we're offering a Complimentary Headshot Booth.

It's a fantastic opportunity to get a free professional headshot! No appointment is necessary—drop by the booth and take advantage of this great offer.

**Photo Booth Hours:**

Thursday, September 12th: 4:00–8:00 PM
Friday, September 13th: 12:00 PM–4:00 PM
Saturday, September 14th: 8:00 AM–12:00 PM

You are reading ***Bridge the GHAPP*** right now. It is a product of the hard work of the Communications Newsletter subcommittee, and we are always looking for new contributors. It can be as simple as sending in a "Pearl" that you've learned regarding physical exam, patient communication, or an aspect of cultural competence. **Do you have a patient vignette with a teachable moment? Please share it with your colleagues!**

The MEC Mentorship program is being restructured to gauge members' needs and goals and increase stakeholder benefits. Details will be included in the upcoming newsletters.

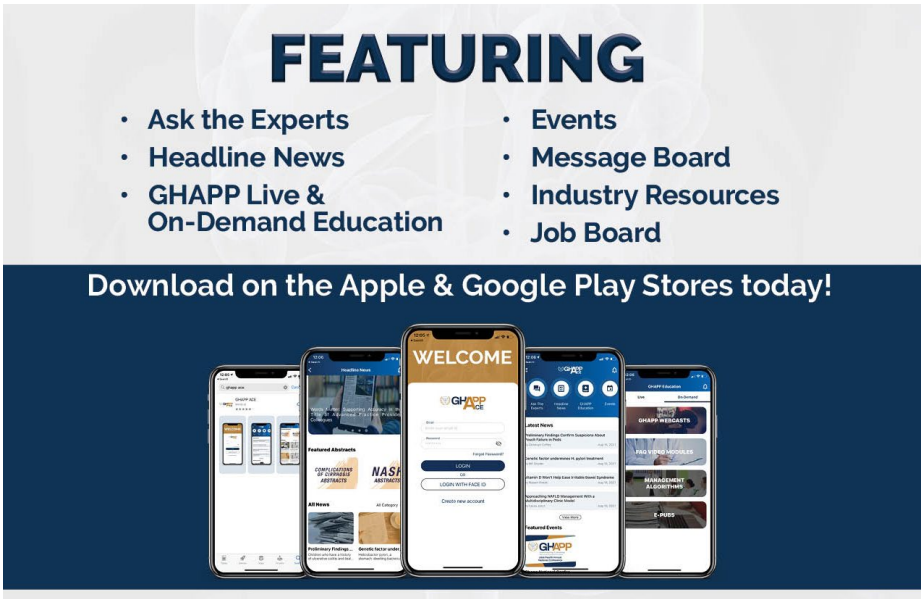
The Abstract subcommittee within the MEC works on reviewing and judging submitted abstracts for the National Conference. Information on the criteria for the abstracts can be found at **www.ghapp.org**. While it is too late to enter this year if you are working on research or plan to, start now to enter an abstract for 2025 and educate your colleagues while competing for an award. A vigorous poster session enriches us all.

MEC Awards subcommittee—what is that, you ask? We are developing a robust award ceremony to be rolled out at the GHAPP National Conference 2025. We are designing an application and evaluation rubric and differing categories of awards. Do you have someone in mind for GI APP or Hepatology APP of the Year? Look for more details in upcoming newsletters.

We hope to see **new members** at the MEC New Member Social Hour on **Friday, September 13th, from 7:00 p.m. to 8:00 p.m. at POSE Rooftop!**

## Register now for a REGIONAL MEETING!

BEST OF
# GHAPP
REGIONAL MEETING SERIES
Gastroenterology & Hepatology
Advanced Practice Providers

# REQUEST A PROGRAM!

*Choose your preferred format: Breakfast or Lunch!*

## Navigating New Horizons: Evolution of MASH Care

**Earn Up to 1.0 AAPA Category 1 CME Credit and 1.00 ANCC Contact Hour!**

### Benefits to Hosting a Meeting:

At no cost to you, this exclusive program offers:

- A live, 1-hour accredited presentation.
- Complimentary food and beverage.
- Program materials and logistical support.

**Interested in a Hosting a Meeting?**
Scan the QR Code or email
**info@mashallianceeducation.org**
to get started!

www.mashallianceeducation.org

info@mashallianceeducation.org

Powered by:

MASH ALLIANCE™

THE GLOBAL NASH COUNCIL · GHAPP · CLDF Chronic Liver Disease Foundation

GHAPP
Gastroenterology & Hepatology
Advanced Practice Providers

# Compassion for IBS-C Project

To learn more and apply, scan the QR code or visit:
www.ghapp.org/grant-opportunities

For more information, please visit:

# www.ghapp.org

Bridge the GHAPP

Gastroenterology & Hepatology
Advanced Practice Providers