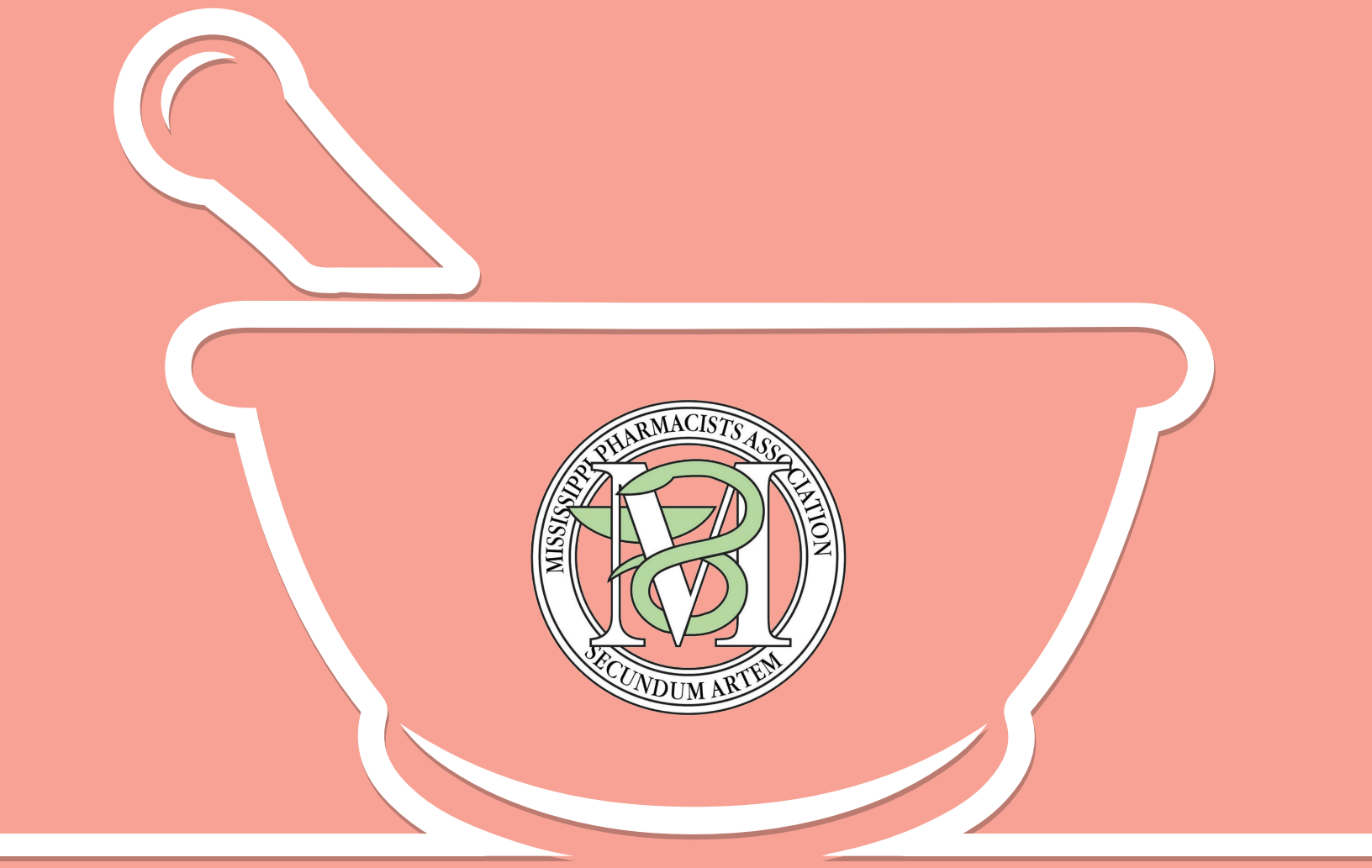
Mississippi Pharmacist

Quarterly publication of the Mississippi Pharmacists Association | Spring 2023



Continuing Education:
Understanding Appropriate Irritable Bowel Syndrome (IBS) Treatment
2.0 CE Hours

Pharmacy Marketing Group, Inc
"Retirement Blindspots"
Some life and financial factors that can sometimes be overlooked.

152nd Annual Convention & Trade Show

Mississippi Pharmacist

VOL XLVIII, No. 1 | Spring 2023 | Growing Stronger Together at MPhA

In this issue...

Advertisers Index

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This emblem designates *Mississippi Pharmacist* is a member of the State Pharmaceutical Editorial Association, recognizing its high journalistic standards in endeavoring to keep its members well informed on all developments relative to the pharmaceutical profession.

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PRESIDENT'S MESSAGE

Members of MPhA,

Actions speak louder than words. This old saying has resonated loudly with me throughout the first part of 2023. MPhA strives to be an organization of action. This action takes place in the three primary areas of advocacy, connection, and education.

The legislative session is in full swing and pharmacy- related bills have been prevalent during the opening weeks. These bills address important matters related to the profession of pharmacy including white bagging, PBM practices, and provisions to test and treat minor, non-chronic health conditions. Many of these bills were brought out of committee and discussed on the House and Senate floors. Ultimately, these bills did not pass but progress was made. MPhA will continue to work to inform legislators of the importance of this legislation and work to ensure that misinformation does not impact the implementation of these important initiatives.

As the new year begins, consider the following actions to maximize your membership in MPhA. Make plans to attend one or more of the events planned for this Spring and Summer. MidWinter, district meetings, and the Annual Convention provide excellent opportunities for you to connect with colleagues and enhance your practice. Join one of the MPhA committees and contribute to the many initiatives of the association. Finally, please contribute to the MPhA PAC and reach out to your representatives to help advocate for the profession of pharmacy when you see future Calls to Action.

It has been and honor to serve as MPhA president. I have been fortunate to work with an amazing group of talented, passionate staff and volunteers during my term. The strength of MPhA is in its membership. I look forward to continuing to serve alongside you as MPhA looks for innovative ways to advocate, educate and connect pharmacists and pharmacy technicians across the state of Mississippi.

With Gratitude,

Tripp Dixon

Tripp Dixon, PharmD

MPhA President

President@mspharm.org

Mississippi Pharmacists Association Awards

The Mississippi Pharmacists Association is accepting nominations through **Wednesday, April 5, 2023** for the following Annual Awards. Awards will be presented during at the **152nd Annual Convention and Trade Show, June 8-10, 2023.**

Bowl of Hygeia

The Bowl of Hygeia Award recognizes pharmacists across the nation who possess outstanding records of civic leadership in their communities and who have made unique contributions to form strong, healthy communities through service and personal leadership. This prestigious award and notable achievement is recognized nationally and sponsored by the American Pharmacists Association and the National Alliance of State Pharmacy Associations, with support from Boehringer Ingelheim. The following criteria should be noted when submitting a nominee for consideration. The recipient of this award:

- Must be a pharmacist, licensed within the jurisdiction in which the award is made.
- Must be living. Awards are not presented posthumously.
- Cannot have previously received the award.
- Has compiled an outstanding record of community service, which, apart from his/her specific identification as a pharmacist, reflects well on the profession.

Hall of Fame Award

The Hall of Fame Award is the most prestigious award presented within MPhA. This award recognizes an exemplary member with a longstanding history of outstanding contributions and commitment to the association. The criteria for this award are:

- The recipient has demonstrated a long-term commitment and service to the association and profession.
- The recipient is not a previous recipient of the award.

Excellence in Innovation Award

The Excellence in Innovation Award sponsored by Upsher-Smith Laboratories, Inc. was introduced as a way to honor a pharmacist who demonstrates innovative and pro-active approaches to enhanced and improved patient care. The criterion for this award is:

- The recipient has demonstrated an innovative pharmacy practice resulting in improved patient care.

J. D. Slater District Achievement Award

This award was created to recognize the MPhA district judged to be the most outstanding as far as service and commitment to the association over the previous year. In honor of J. D. Slater, and sponsored by the association, this award exemplifies professional involvement, outreach, and engagement. The recipient of this award should have the following qualification:

- A district that has demonstrated outstanding service to the profession and association.

Distinguished Young Pharmacist Award

This award, sponsored by Pharmacists Mutual, recognizes a practicing pharmacist with superior achievement, within 10 years of their terminal pharmacy degree. Nominees for this award should be persons who exemplify professional, pharmacy service and have demonstrated the following:

- Outstanding service in pharmacy practice.
- Service in professional organizations.
- Outstanding service to the community.
- Services/interaction with other health care workers.

Pharmacy Technician Award

This award, established in 2003, recognizes pharmacy technicians who exhibit professional characteristics inherent of a model pharmacy technician. The nominee should be a person who has demonstrated professional competency and who is actively working to help establish the role of the technician in pharmacy services. Factors to be considered for this award sponsored by MPhA are:

- Service to his/her organization and or area of patient service.
- Involvement in committees and technician leadership.
- Significant contributions to the promotion of pharmacy.

Student Pharmacy Award

This award recognizes a student pharmacist who has demonstrated proven leadership ability and who represents the very best attributes and accomplishments of pharmacy students. Sponsored by MPhA, this award honors a student of pharmacy who has been actively involved in association activities and helped to promote the advancement of pharmacy. The student must:

- Be a current student member of MPhA.
- Be a leader and involved in association activities to promote the advancement of the profession of pharmacy.

Spirit of Pharmacy Award

This award, sponsored by MPhA, recognizes a service-oriented and hard-working member that has demonstrated an extraordinary commitment to our association and volunteer activities. The recipient of this award must:

- Be a current member of MPhA.
- Have made significant contributions to the association and professional activities.

Member of the Year Award

Sponsored by MPhA, this award is presented to a member who has demonstrated impeccable commitment to the association, dedicated his/her personal time and energy to furthering the objectives of the association, and is active in all aspects of the association. The recipient of this award must have:

- Demonstrated commitment and service to the association, over and beyond expectations per the member's role.
- Served on one or more committees.
- Dedicated personal time to member outreach and recruitment.

Mississippi Pharmacists Association 2023 Awards
In Recognition of Excellence

The Mississippi Pharmacists Association is accepting nominations through **Wednesday, April 5, 2023** for the following Annual Awards. Awards will be presented during the **152nd Annual Convention and Trade Show, June 8-10, 2023.**

******* Please refer to the *Awards Description* to view all award criteria. *******

This nomination form is for the following awards (*check one box*):

- ☐ Bowl of Hygeia Award – *Sponsored by American Pharmacists Association and National Alliance of State Pharmacy Associations, with support from Boehringer Ingelheim*
- ☐ Hall of Fame Award
- ☐ Excellence in Innovation Award – *Sponsored by Upsher-Smith Laboratories, Inc.*
- ☐ J. D. Slater District Achievement Award
- ☐ Distinguished Young Pharmacist Award – *Sponsored by Pharmacists Mutual*
- ☐ Pharmacy Technician Award
- ☐ Student Pharmacy Award
- ☐ Spirit of Pharmacy Award
- ☐ Member of the Year Award

Section 1 – Nominee Information *(please fill out as best possible)*

Name: _____ Phone: _____

Address: _____ City: _____

State: _____ Zip: _____ Email: _____

Designation: ☐ Pharmacist ☐ Pharmacy Technician ☐ Pharmacy Student ☐ Other _____

This person is aware that I have nominated him/her *(not required)*: ☐ YES ☐ NO

I am forwarding or attaching a nomination letter: ☐ YES ☐ NO

Section 2 – Nominator Information *(person submitting nomination)*

Name: _____ Phone: _____

Email: _____

→ **Please include a nomination letter and/or additional documentation that supports your nomination.**
Refer to the award descriptions to view criteria for each award.

The nomination form and attachments must be *received* by the MPhA by Wednesday, April 5, 2023 at 5:00 pm.

Mail nomination form and attachments to:
Mississippi Pharmacists Association
Attn: Nominations and Awards Committee
PO Box 16861
Jackson, MS 39236

OR Submit electronically at www.mspharm.org/awardnominations
and email supporting documentation to info@mspharm.org

For MPhA Use Only
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MPhA Member? _____
Committee Review _____
Status _____

EXECUTIVE DIRECTOR'S LETTER

Happy New Year!

The profession of pharmacy appeals to so many people in numerous ways. One shared commonality is the sincere joy of helping and serving people in our community. This year's focus is on being intentional and choosing joy. All pharmacists across the state are in pursuit of work-life balance. At the beginning of every year, we often take an assessment of goals we've met and accomplishments we've seen in the past year and devise plans and goals for the coming year. Setting goals is like building a road map. It gives us a chance to consider where we're at, what we want, and how to get there. Without a plan, we're more likely to wander aimlessly or waste time on tactics that won't work. Our goals at MPhA for 2023 remain concrete to connect you and fellow professionals throughout the pharmacy community, provide a variety of continuing education programs and advocate on behalf of our pharmacists. We are the voice for Mississippi pharmacists in Congress and as well as our state legislature.

I have been engaged in our current legislative affairs, actively providing insight to potential resolution to workforce issues in our profession and strategies to increase our membership. We had an exciting Pharmacy Day at the Capitol on January 17, 2023.

The MPhA has been working on several bills this year, the main three being HB 1316 (White Bagging), HB 1317 (Test and Treat) and SB 2484 (PBM reform). These bills were reported out of the respective committees to which they were assigned and were active on the calendar. Rep. Lee Yancey, Chairman of the House Drug Policy Committee, and Rep. Hank Zuber, Chairman of the House Insurance Committee, advised that they hold hearings this summer with respect to HB 1316 and accordingly Chairman Yancey did not bring the bill up for consideration before the House. Chairman Zuber did indicate that he has an Omnibus bill working in which he may include some of the pertinent language of HB 1316 this year. We are working closely with him in this regard. Chairman Yancey did present HB 1317 to the House; however, after serious debate, he moved to lay the bill on the table. Since it was deadline day, it effectively killed the bill for this session. Chairman Yancey is very much in favor of test and treat and has committed to working with our Association and others in interest to pass this legislation next session. SB 2484 died on the calendar. Sen. Hob Bryan, Chairman of the Senate Public Health Committee, the committee to which this bill was assigned, is in favor of this legislation. We are working with him to amend other bills still pending to include pertinent parts of SB 2684. We must stay focused and stay in the race. It is critical that you allow your voice to be heard by calling your legislators.

Each day, I am extremely grateful to work in the wonderful profession of pharmacy and to serve as your Executive Director. MPhA remains committed to offering you services that you expect and deserve, quality continuing education, current pharmacy news, networking, and advocacy efforts.

Our Mid-Winter conferences are underway in Jackson, Biloxi, and Oxford. They have been extremely informative and impactful. All roads lead to Oxford for our exciting Annual Convention & Trade Show June 8 – June 10.

Thank you for what you do daily for our profession. I feel one of the greatest opportunity the Association offers is networking. I challenge each of you to get involved. We are better together, so let's move the profession of pharmacy forward.

Mona Arnold-McBride

Mona Arnold-McBride, PharmD
Executive Director

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The Ballad of Snowbirds and Audits

The winter months have many pharmacies mailing prescriptions to their snowbird patients who leave their northern nests for more hospitable climates. Pharmacies want to keep these patients happy and coming back when the weather is nicer and may look to mailing maintenance medications to them when they have migrated out of state. Although these pharmacies may think they are doing the right thing for patient care, and their business, they may also be setting themselves up for audit failure.

Unfortunately, this does not just apply to northern states with snowbird patients. Many states now have laws that require nonresident pharmacies to obtain a license to ship, mail, deliver, or dispense prescription medications into their states. Auditors take advantage of these laws to recoup money from well-meaning pharmacies who may not even know that mailing a prescription out of state is a problem! For pharmacies situated close to the state border, delivering into a neighboring state carries the same risks. PAAS National® has seen these claims cited as law violations with limited appeal options.

PAAS Tips:

- Before mailing/delivering prescriptions out of state, it is a good idea to check with that state's Board of Pharmacy to see if there are any licensure requirements for doing so.
- Be aware of your contract obligations and which PBMs do not allow mailing of prescriptions to patients.
- The COVID-19 pandemic had many PBMs make concessions to allow mailing during the Public Health Emergency (PHE). Keep up to date on concession expirations by downloading the PAAS *COVID-19 PBM/Payers Concessions Chart*[1], available at paasnational.com/covid19.
- PAAS Audit Assistance members can access the following resources on the Member Portal:
    - Ensure you can prove, on an audit, the patient received their medication with tracking information that links to the prescription. See the January 2022 Newsline article, *Mailing Prescriptions: How Do You Prove Patient Receipt?*[2]
    - Know the rules surrounding automatic mailing, especially for Medicare Part D patient, and review the September 2022 Newsline article, *Automatic Mailing for Part D Patients*[3], for specific information.

PAAS National® is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact us today at (608) 873-1342 or info@paasnational.com to see why membership might be right for you.

By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

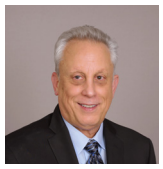
References:

1. https://paaswp.s3.amazonaws.com/downloads/covid19chart.pdf
2. https://portal.paasnational.com/Paas/Newsletter/Go/949
3. https://portal.paasnational.com/Paas/Newsletter/Go/1055

2022 Recipients of the "Bowl of Hygeia" Award


Ronnie E. Opolka Sr.
Alabama


Kyla Newland
Alaska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Arizona


Brenda Dickerson McCrady
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California


Joseph Saseen
Colorado


Sean M. Jeffery
Connecticut


Heidi Lueking
Delaware


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James Tallman
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Pennsylvania


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Jeffrey Bratberg
Rhode Island


John W. Pugh
South Carolina


Cari Mack
South Dakota

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Tennessee

Raymond Carvajal
Texas

Elizabeth W. Young
Utah

Jeffrey Firlik
Vermont

Catherine Herbert Cary
Virginia

Cynthia A. Clegg
Washington

Ginger G. Scott
West Virginia

Jeanine Krueger
Wisconsin

William (Bill) Wenke
Wyoming

Photo Not Available
William Moore
Oklahoma

APhA Foundation

NASPA
NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA History Hall located in Washington, DC.

Congratulations

2023 Scholarship Winners

Each student listed received a $3,000 scholarship.

Cameron Buss University of Mississippi
Caitlin Rohrbaugh University of Iowa
Andrew Smith Auburn University
Alexandria Ocker Binghamton University
Destiny Rogers Samford University
Caroline Eason Univ. of North Carolina at Chapel Hill
Casey Hourigan Univ. of the Incarnate Word
Diana Ghanimah Medical College of Wisconsin
Katelyn Sutton Duquesne University
Gunjan Patel University of Illinois at Chicago
Haley Weaver Harding University
Jackson Beach Southwestern Oklahoma State Univ.
Lauren Williams University of Kentucky
Mohit Kumar University of Georgia
Moriah Willis University of Oklahoma
Makenna Rose Southwestern Oklahoma State Univ.
Olukemi Omotola University of Charleston
Ngozi Ihemeson University of Illinois at Chicago
Olivia Hanna Nova Southeastern University
Rui Hua Zheng Northeastern University

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2023
MID-WINTER HIGHLIGHTS

CONTINUING EDUCATION

Understanding Appropriate Irritable Bowel Syndrome (IBS) Treatment

The 2022 American Gastroenterological Association (AGA) Clinical Practice Guidelines on the Management of Irritable Bowel Syndrome: What's New?

AUTHORS

Amy Ly-Ha, PharmD, PGY1 Community-Based Resident at The University Mississippi School of Pharmacy

Sophie Durham, PharmD, PGY1 Community-Based Resident at The Mississippi State Department of Health

OBJECTIVES

1. Recognize the first, second, and third-line treatments for IBS-C and IBS-D using the AGA's Clinical Decision Support Tool.
2. Identify the drugs recommended by the 2022 AGA Clinical Practice Guidelines for the treatment of IBS-C and IBS-D.
3. Describe the mechanism of action for the drugs mentioned in the AGA guidelines.

Overview

Irritable bowel syndrome (IBS) is a disorder of gut-brain interaction characterized by chronic abdominal pain and altered bowel habits.[1] Patients can be classified into four IBS subtypes: IBS with predominant constipation (IBS-C), IBS with predominant diarrhea (IBS-D), IBS with mixed bowel habits (IBS-M), and unclassified IBS. With a worldwide prevalence of 11.2% based on a meta-analysis of 260,960 individuals, IBS conveys significant burdens to both patients and society.[2] Its marked reduction in the quality of life for patients is emphasized in an international survey where many respondents answered that they would exchange 25% of their remaining life to receive a treatment that would make them asymptomatic.[3]

Although IBS is a chronic disease with no known cure, treatments are available to provide relief from symptoms and improve the quality of life. Pharmacists can use these resources to manage and support patients with IBS. In July 2022, the American Gastroenterological Association (AGA) published updated guidelines for the pharmacologic management of IBS-C and IBS-D along with a clinical decision support tool. In these guidelines, the AGA uses the term "recommend" to indicate strong recommendations and the term "suggest" to indicate conditional recommendations. A strong recommendation means that most individuals should receive the intervention while a conditional recommendation means shared decision-making should be implemented based on patient needs. Furthermore, the AGA indicates its certainty in the evidence with the terms "high", "moderate", "low", and "very low". A high certainty in the evidence means that the AGA is confident that the true effect lies close to that of the estimate of the effect. A moderate certainty designates that the true effect is likely to be close to the estimate of the effect; however, there remains a possibility that the true effect is substantially different. A low certainty represents the possibility that the true effect may be substantially different from the estimate of the effect.[6] Although other guidelines for the management of IBS exist, such as the 2021 clinical guideline published by the American College of Gastroenterology (ACG), this article will focus on the updated AGA guidelines.

Clinical Decision Support Tool[4]

In the management of all patients with IBS, healthcare professionals must establish relationships with their patients to develop trust and promote positive patient experiences. Providing patient education and reassurance encourages patients to accept their diagnosis and supports self-efficacy. Furthermore, healthcare professionals should encourage patients with IBS to pursue lifestyle and dietary modifications. Lifestyle modifications include exercise, sleep, and stress reduction. Dietary modifications can also improve IBS symptoms. Short-chain carbohydrates are poorly absorbed in the intestinal lumen. Their osmotic activity can lead to rapid fermentation, which induces abdominal pain and bloating. Therefore, a diet low in fermentable oligo-, di-, and monosaccharides and polyol, also known as a low FODMAP diet, is recommended to relieve these IBS symptoms.[5] Common examples of high FODMAP foods include cow's milk, wheat, apples, and honey. A low FODMAP diet consists of three phases: restriction, reintroduction, and personalization. In the restriction phase, a reduction of FODMAP in the patient's diet is implemented to assess whether IBS symptoms are associated with FODMAP intake. Patients whose IBS symptoms improve in the restriction phase will progress onto the reintroduction phase where tolerance to specific FODMAP groups is assessed at different times. Finally, the patient's diet is personalized based on the results from the reintroduction phase.[5] Soluble fiber is also recommended to relieve global symptoms of IBS and can be found in psyllium, oat bran, and barley. Psyllium is initially dosed off-label in the management of IBS-C as three to four grams per day. This can be titrated every one to two weeks to achieve a recommended daily fiber intake of 25 to 35 grams.

An osmotic laxative, such as polyethylene glycol (PEG), is the first-line treatment for constipation and/or mild IBS-C in the management of IBS-C according to the AGA's clinical decision support tool. Second-line agents used in moderate IBS-C are secretagogues like linaclotide, lubiprostone, plecanatide, or tenapanor. Third-line therapy for IBS-C consists of tegaserod.

Loperamide and bile acid sequestrants are the first-line treatments for diarrhea in the management of IBS-D according to the AGA's clinical decision support tool. Second-line agents used in moderate IBS-D include rifaximin, low-dose tricyclic antidepressant (TCA), and eluxadoline. Third-line therapy for IBS-D consists of alosetron.

Antispasmodics, such as hyoscyamine or peppermint oil, is used as a first-line option in the treatment of abdominal pain in the management of patients with IBS-C or IBS-D. Furthermore, if persistent abdominal pain and/or psychological symptoms remain despite using the respective second-line or third-line therapies, adding or switching to a low-dose TCA if absent from the current regimen, a serotonin-norepinephrine reuptake inhibitor (SNRI), or brain-gut behavior therapies can be considered based on patient needs. A visual representation of this clinical decision support tool can be found in Table 1.

Pharmacologic Management of Irritable Bowel Syndrome with Predominant Constipation (IBS-C)[6]

IBS-C is a subtype of IBS that accounts for more than one-third of IBS cases. The recently published AGA clinical practice guideline for IBS-C addresses nine drugs and drug classes relevant to IBS-C.[6] This guideline used the United States Food and Drug Administration (FDA) endpoint as an outcome of interest when reviewing studies to formulate recommendations. The FDA defined the IBS-C responder endpoint as a participant who reports both a 30% or more reduction in average daily worst abdominal pain scores and an increase of one or more spontaneous bowel movements per week compared to baseline for more than six of 12 weeks.[6] A summary of these recommendations is listed in Table 2.

Linaclotide (Linzess®)

Linaclotide and its active metabolites, like plecanatide, bind and agonize guanylate cyclase-C, which leads to electrolyte and fluid secretion.[12] In patients with IBS-C, the AGA suggests using linaclotide with high certainty in the evidence. Across 4 RCTs, 1,307 patients were treated with linaclotide and 1,305 patients were treated with placebo. Patients who received linaclotide had greater symptom relief based on the IBS-C FDA responder endpoint (RR, 0.81; 95% CI, 0.77-0.85) as the FDA endpoint was met by 34% in the linaclotide group versus 18.8% in the placebo group.[6] Diarrhea was the most common adverse event. Linaclotide is FDA-approved for the treatment of chronic idiopathic constipation and IBS-C in adults. For IBS-C, linaclotide is initially dosed at 290 mcg by mouth once daily at least 30 minutes before the first meal of the day on an empty stomach.[12] This dose may be reduced to 145 mcg once daily if the patient develops diarrhea. Administration of linaclotide with a high-fat meal may worsen side effects.

Tenapanor (Ibsrela®)

As a small-molecular inhibitor of the gastrointestinal sodium/hydrogen exchange isoform 3, tenapanor acts locally to reduce sodium absorption from the small intestines and colon. This results in increased water secretion into the intestinal lumen, thus accelerating intestinal transit time and softening stool consistency.[7] In patients with IBS-C, the AGA suggests using tenapanor with moderate certainty in the evidence. In three placebo-controlled randomized controlled trials (RCTs), a total of 688 patients with IBS-C were treated with tenapanor and 684 patients were treated with placebo for 12 weeks.[8-10] These studies found that patients who took tenapanor experienced improved symptom relief based on the IBS-C FDA responder endpoint (RR, 0.84; 95% CI, 0.79-0.90) as the FDA endpoint was met by 34.1% in the tenapanor group compared to 21.7% in the placebo group.[6] These studies also demonstrated diarrhea as the most common adverse event with tenapanor compared to placebo.[8-10] Tenapanor is FDA-approved for the treatment of IBS-C in adults. It is dosed at 50 mg by mouth twice daily and should be given immediately before breakfast or the first meal of the day and immediately before dinner.[7] Potassium levels should be monitored in patients with renal impairment.

Table 1: Clinical Decision Support Tool for IBS Treatment[4]

	IBS-C	IBS-D
First-Line (Mild)	For Constipation Osmotic Laxatives (e.g., PEG)	For Diarrhea Loperamide, Bile Acid Sequestrant (e.g., colestipol)
	For Abdominal Pain Antispasmodics (e.g., hyoscyamine, peppermint oil)	For Abdominal Pain Antispasmodics (e.g., hyoscyamine, peppermint oil)
Second-Line (Moderate)	Secretagogues (linaclotide, lubiprostone, plecanatide, tenapanor	Rifaximin, low-dose TCA (e.g., amitriptyline, desipramine), eluxadoline
Third-Line	Tegaserod	Alosetron
If abdominal pain and/or psychological symptoms persist despite the addition of second-line and/or third-line therapies	Add or switch to low dose TCA (if not already taking), SNRI, brain-gut behavior therapies (e.g., cognitive behavior therapy, hypnosis)	

Table 2: Summary of Recommendations for IBS-C[6]		
New or Updated Recommendations	**Strength of Recommendations**	**Certainty in Evidence**
In patients with IBS-C, the AGA recommends using linaclotide.	Strong	High
In patients with IBS-C, the AGA suggests using tenapanor.	Conditional	Moderate
In patients with IBS-C, the AGA suggests using plecanatide.	Conditional	Moderate
In patients with IBS-C, the AGA suggests using tegaserod. Implementation Remark: Tegaserod was reapproved for women less than 65 years of age without a history of cardiovascular ischemic events.	Conditional	Moderate
In patients with IBS-C, the AGA suggests using lubiprostone.	Conditional	Moderate
In patients with IBS-C, the AGA suggests using polyethylene glycol (PEG) laxatives.	Conditional	Low

Plecanatide (Trulance®)

Plecanatide and its active metabolite are guanylate cyclase-C agonists. Activation of this enzyme increases cyclic guanosine monophosphate levels (cGMP). An intracellular elevation of cGMP activates the cystic fibrosis transmembrane conductance regulator, which leads to chloride and bicarbonate secretion into the intestinal lumen. This results in increased intestinal fluid along with accelerated transit.[11] In patients with IBS-C, the AGA suggests using plecanatide with moderate certainty in the evidence. In two RCTs, a total of 814 patients with IBS-C were treated with plecanatide at the three milligram dose and 818 patients were treated with placebo for 12 weeks. Compared to placebo, patients who received plecanatide experienced improved symptom relief based on the IBS-C FDA responder endpoint (RR, 0.87; 95% CI, 0.83-0.92) as the FDA endpoint was met by 27.4% in the plecanatide group and 16.9% in the placebo group.[6] Diarrhea was the most common adverse event with plecanatide compared to placebo. Plecanatide is FDA-approved for the treatment of chronic idiopathic constipation and IBS-C in adults. It is dosed at 3 mg by mouth once daily by mouth with or without food.[11]

Tegaserod

Note: The manufacturer of tegaserod (Zelnorm®) voluntarily withdrew this medication from the market in June 2022 due to business decisions. Patients will have access to the existing supply until it is depleted.

As a partial agonist of the 5-HT4 receptor, tegaserod stimulates gastrointestinal motility and intestinal fluid secretion.[13] In patients with IBS-C, the AGA suggests using tegaserod with moderate certainty in the evidence. Across four RCTs, a total of 1,450 women received tegaserod and 1,433 received placebo. Patients who received tegaserod experienced improved symptom relief based on the IBS-C FDA responder endpoint (RR, 0.87; 95% CI, 0.81-0.93) as the FDA endpoint was met by 35.1% in the tegaserod group versus 23.4% in the placebo group.[6] In 2007, the FDA requested tegaserod's withdrawal from the market as safety analyses found a higher incidence of cardiovascular ischemic events in patients taking tegaserod compared to placebo. In 2019, the FDA re-approved tegaserod for IBS-C in females less than 65 years of age without a history of ischemic cardiovascular disease (e.g., myocardial infarction or stroke) and who have no more than one risk factor for cardiovascular disease (e.g., active smoking, hypertension, diabetes, or obesity).[13] The FDA approval was restricted to this population as safety and efficacy have not been established in males. It is dosed 6 mg by mouth twice daily and should be administered 30 minutes or more before meals.

Lubiprostone (Amitiza®)

With local actions, lubiprostone is a chloride channel type two activator that increases chloride influx into the gastrointestinal tract lumen, thus accelerating intestinal transit. Lubiprostone is FDA-approved for the treatment of chronic idiopathic constipation in adults. It is also approved for IBS-C in females 18 years of age and older at a dosage of 8 mcg by mouth twice daily with food and water.[15] Lubiprostone was not approved for IBS-C in males as its efficacy was not conclusively demonstrated in this patient population. In patients with IBS-C, the AGA suggests using lubiprostone with moderate certainty in the evidence. Across two RCTs that included 1,154 patients with IBS-C, lubiprostone was superior compared to placebo for a modified FDA response that evaluated abdominal pain and spontaneous bowel movements response (RR, 0.88; 95% CI, 0.79-0.96). However, lubiprostone was not superior to placebo in terms of spontaneous bowel movement frequency (RR, 0.90; 95% CI, 0.75-1.10).[6] Dyspnea and syncope have been reported and should be counseled on.

Polyethylene Glycol Laxatives

PEG acts as an osmotic laxative to increase water retention in the stool. PEG without electrolytes is available over-the-counter in the United States. In patients with IBS-C, the

AGA suggests using PEG laxatives with low certainty in the evidence. One placebo-controlled trial consisting of 68 patients who received PEG 3350 with electrolytes and 71 patients who received placebo demonstrated improvement in spontaneous bowel movement frequency with PEG than with placebo.[6] Due to the lack of larger studies, the AGA's overall certainty of the evidence is low.

Pharmacologic Management of Irritable Bowel Syndrome with Predominant Diarrhea (IBS-D)[15]

IBS-D is one of the main subtypes of IBS, accounting for 30-40% of all IBS cases. The guidelines provide new or updated recommendations for eluxadoline and rifaximin and present a review of the evidence and recommendations for alosetron and loperamide. The guidelines used the FDA responder endpoint for decision making, which was defined as a participant who reports both a ≥30% reduction in average daily worst abdominal pain scores and a ≥50% reduction in number of days per week with at least 1 stool that has a consistency of type 6 or 7 according to the Bristol Stool Form Scale (BSFS). A summary of these recommendations can be found in Table 3.

Eluxadoline (Viberzi®)[16]

Eluxadoline is a non-narcotic that works as a mu- and kappa-opioid agonist and delta-opioid receptor antagonist to decrease visceral hypersensitivity and control GI motility. The AGA suggests using eluxadoline in patients with IBS-D. In two large phase 3 trials, 808 patients with IBS-D were randomized to receive eluxadoline 100 mg twice daily and 809 participants were given placebo twice daily. A greater proportion of patients receiving eluxadoline were FDA endpoint responders compared to placebo (27.2% vs 16.7%; RR, 0.87; 95% CI, 0.83–0.92). Researchers used a global assessment to measure adequate relief of IBS-D symptoms and found that a greater proportion of patients who received eluxadoline reported relief for ≥ 6 of the first 12 weeks compared to placebo (38.4% vs 29.2%; RR, 0.87; 95% CI, 0.81– 0.93). These studies evaluated 3 individual symptoms: improvement in abdominal pain, stool consistency, and urgency. While researchers found a clinically significant improvement in outcomes of stool consistency (RR, 0.84; 95% CI, 0.80–0.88) and ≥ 50% urgency-free days (RR, 0.84; 95% CI, 0.78–0.90), they found that eluxadoline has less of an effect on improvement in abdominal pain (RR, 0.92; 95% CI, 0.84–1.00).[17] Thus, eluxadoline may be more beneficial for use in patients with predominant and bothersome diarrhea than in patients with more severe abdominal pain. There were 5 pancreatitis and 8 Sphincter of Oddi spasm (SOS) events in patients treated with eluxadoline and none in those receiving placebo. These cases were associated with the absence of a gallbladder or history of alcohol abuse, so eluxadoline is now contraindicated in patients without a gallbladder or patients who drink more than 3 alcoholic beverages per day.[17] Eluxadoline is FDA-approved for the treatment of IBS-D at a dose of 100 mg twice daily in most patients. The dose is reduced to 75 mg twice daily in patients with mild or moderate hepatic impairment and patients receiving concomitant OATP1B1 inhibitors.

Rifaximin (Xifaxan®)[18]

Rifaximin is the only FDA-approved, nonsystemic IBS-D treatment that alters the microbiome by blocking one of the steps in the transcription of bacterial DNA to RNA, inhibiting protein synthesis and bacterial growth. The AGA suggests using rifaximin in patients with IBS-D and in patients with an initial response to rifaximin who develop recurrent symptoms. Rifaximin is FDA-approved for treatment of IBS-D at a dose of 550 mg 3 times per day for 14 days. The 2014 technical review examined 3 RCTs that compared rifamixin to placebo for treatment of IBS-D. Outcomes such as spontaneous bowel movement and complete spontaneous bowel movement responder rates, health-related quality of life improvement, and diarrhea leading to withdrawal could not be assessed based on the available data at that time.

A subsequent placebo-controlled, 51-week, phase 3 RCT was conducted to assess the safety and efficacy of repeat treatment after clinical response and subsequent symptom relapse with rifaximin for IBS-D. A greater proportion of patients treated with rifaximin did not experience symptom recurrence up to 10 weeks after the first treatment (durable response) than patients on placebo (17.1% vs 11.7%; RR, 0.94; 95% CI, 0.88–1.00) or throughout the retreatment phase of the study (13.2% vs 7.1%; RR, 0.93; 95% CI, 0.88–0.99). Re-treatment with rifaximin was associated with adequate relief of abdominal pain and improvement in urgency, while it fell short with improvement in stool consistency and bloating. Patients who experience a recurrence of symptoms can be retreated up to 2 times with the same dosage regimen.

Alosetron (Lotronex®)[19]

Alosetron is a selective 5-HT3 receptor antagonist that inhibits the activation of non-selective cation channels, resulting in the modulation of the enteric nervous system. By blocking the activation of these channels, alosetron regulates visceral pain, colonic transit, and gastrointestinal secretions. The AGA suggests using alosetron in women with severe IBS-D who have not responded to conventional therapy and have symptoms that are severe, which is defined as 1 or more of the following: frequent and severe abdominal pain/discomfort, frequent bowel urgency or fecal incontinence, and/or disability or restriction of daily activities due to IBS. Because the effectiveness of alosetron has not been confirmed in men, its use is restricted to women. Alosetron was originally FDA-approved in 2000 for the treatment of IBS-D in women but was voluntarily withdrawn due to reports of ischemic colitis and serious complications of constipation.

The FDA approved its reintroduction for the treatment of IBS-D in women under a risk-management program in 2002. The modified Risk Evaluation and Mitigation Strategies (REMS) program requires that providers review the materials in the REMS training kit and complete the "Prescriber Completion of Lotronex REMS Program Training Form." The form should be sent by email or fax or submitted on the website upon completion. The training

packet includes the REMS letter for Healthcare Providers, the prescriber education slide deck, the safety information Fact Sheet for Prescribers, the Patient Education Sheet, and the training completion form. The patient education sheet should then be reviewed with the patient.

A post-marketing study evaluating the safety of alosetron over 9 years shows that the cumulative adjudicated incidence of ischemic colitis and adjudicated incidence rate of serious complications of constipation appear to have declined over time with an adjudicated cumulative incidence of 1.03 cases per 1000 patient-years and 0.25 cases per 1000 patient-years, respectively.20 The initial recommended starting dose is 0.5 mg twice daily. Patients experiencing constipation must stop taking the medication until symptoms resolve and then restart the medication at 0.5 mg daily. If constipation persists at the lower dose, the medication should be discontinued. If the original symptoms do not resolve after 4 weeks, the dose can be increased to 1 mg twice daily. If symptoms persist at this increased dose, alosetron should be discontinued. No new studies of alosetron for the treatment of IBS-D were identified since the 2014 technical review.

Loperamide

Loperamide is a synthetic peripheral opioid receptor agonist that acts by inhibiting peristalsis and antisecretory activity and prolonging intestinal transit time. The AGA suggests using loperamide in patients with IBS-D. No new studies have evaluated the efficacy of loperamide in the management of IBS-D. This review was based on 2 small studies that were published in 1987. These studies found that loperamide is associated with improvements in abdominal pain and stool consistency but did provide global improvement of symptoms of IBS and urgency; however, details of how improvement in symptoms was determined were poorly described. Loperamide is FDA-approved for the treatment of patients with acute, chronic, and traveler's diarrhea. The optimal dose for its use in IBS-D treatment is not known and can vary between patients based on their symptom patterns.

Pharmacologic Management of IBS[6,15]

Both the IBS-C and IBS-D clinical practice guidelines from the AGA address three drug classes for use in either patient populations. These drug classes are tricyclic antidepressants, selective serotonin reuptake inhibitors, and antispasmodics.

Tricyclic Antidepressants

In patients with IBS, the AGA suggests using TCAs with low certainty in the evidence. Their peripheral and central actions can affect intestinal motility, secretion, and sensation.[6,15] Compared to placebo, TCAs were associated with greater abdominal pain relief. The selection of a TCA should be individualized to the patient's needs and preferences. Secondary amine TCAs, like desipramine and nortriptyline, are associated with a lower risk of anticholinergic side effects; therefore, they may be better tolerated in patients with IBS-C.[6]

Selective Serotonin Reuptake Inhibitors (SSRIs)

In patients with IBS, the AGA suggests against using SSRIs as they did not significantly improve global symptoms of IBS or abdominal pain.[6,15]

Antispasmodics

In patients with IBS, the AGA suggests using antispasmodics with low certainty in the evidence. These agents have been used to reduce IBS-associated abdominal pain. Antispasmodics available in the United States include hyoscyamine, dicyclomine, and peppermint oil.6,15 Peppermint oil comes in various forms; however, studies have evaluated the use of oral capsules in patients with IBS.[21]

Table 3: Summary of Recommendations for IBS-D[15]

New or Updated Recommendations	Strength of Recommendations	Certainty in Evidence
In patients with IBS-D, the AGA suggests using eluxadoline. Implementation Remark: Eluxadoline is contraindication in patients without a gallbladder or those who drink more than 3 alcoholic beverages per day.	Conditional	Moderate
In patients with IBS-D, the AGA suggests using rifaximin.	Conditional	Moderate
In patients with IBS-D with an initial response to rifaximin who develop recurrent symptoms, the AGA suggests retreatment with rifaximin.	Conditional	Moderate
In patients with IBS-D, the AGA suggests using alosetron. Implementation remark: Alosetron is restricted for use in women with severe IBS-D under a risk-management program.	Conditional	Moderate
In patients with IBS-D, the AGA suggests using loperamide.	Conditional	Very Low

Conclusion

There exist many opportunities for pharmacists to assist patients with IBS. Pharmacists can form and strengthen relationships necessary to support the patients in their IBS management. Furthermore, pharmacists can also help patients develop treatment plans to provide symptomatic relief. Therefore, the recommendations provided by the AGA guidelines can be used to provide a foundation for decision-making; however, treatment must be individualized to the patient.

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Understanding Appropriate Irritable Bowel Syndrome (IBS) Treatment

Instructions: After reading the continuing education article, quizzes can be taken at mspharm.org or detach this page. A grade of 70% or better is required to earn 2.0 hours of continuing education credit. This is a free service for MPhA members.

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1. How should plecanatide be administered for the treatment of IBS-C?
    A. By mouth irrespective of meals
    B. By mouth during meals
    C. By mouth immediately prior to breakfast or the first main meal of the day and immediately prior to dinner
    D. By subcutaneous injection

2. Which pharmacological agent does the AGA recommend use of in patients with IBS-C based on its clinical practice guideline?
    A. Lubiprostone
    B. Linaclotide
    C. Tenapanor
    D. Plecanatide

3. Which patient population is lubiprostone FDA-approved for regarding the treatment of IBS-C?
    A. Females who are 18 years of age or older
    B. Females who are younger than 65 years of age who do not have a history of ischemic cardiovascular stroke and who do not have more than one cardiovascular disease risk factor
    C. Males who are 18 years of age or older
    D. Males who are younger than 65 years of age who do not have a history of ischemic cardiovascular stroke and who do not have more than one cardiovascular disease risk factor

4. AM is a 40-year-old female with IBS-C. She has a past medical history of diabetes and hypertension. She smokes one pack of cigarettes per day. Why is AM an ineligible candidate for therapy with tegaserod?
    A. Tegaserod is used in the treatment of IBS-D and not IBS-C.
    B. AM is a female.
    C. AM is too old to be on tegaserod.
    D. AM has more than one risk factor for cardiovascular disease.

5. Why should linaclotide be given on an empty stomach?
    A. Administration with a high-fat meal may increase linaclotide's absorption.
    B. Administration with a high-fat meal may decrease linaclotide's absorption.
    C. Administration with a high-fat meal may worsen linaclotide's side effects.
    D. Administration with a low-fat meal may worsen linaclotide's side effects.

6. According to the AGA's clinical decision support tool, what drug would you recommend for an individual with mild IBS-C who is experiencing abdominal pain?
    A. Sertraline
    B. Linaclotide
    C. Amitriptyline
    D. Hyoscyamine

7. Which option best represents linaclotide's mechanism of action in the management of IBS-C?
    A. Agonist of guanylate cyclase-C
    B. Small-molecular inhibitor of the gastrointestinal sodium/hydrogen exchange isoform 3
    C. Partial agonist of the 5-HT4 receptor
    D. Activator of chloride channel type 2

8. What is the most common adverse event associated with linaclotide?
    A. Diarrhea
    B. Dry mouth
    C. Skin rash
    D. Hypotension

9. In which patient population is treatment with eluxadoline contraindicated?
    A. Patients with renal impairment
    B. Patients with a history of MI or stroke
    C. Patients who drink more than 3 alcoholic beverages per day
    D. Patients without a spleen

10. What is the FDA-approved duration of treatment with rifaximin for the treatment of IBS-D?
    A. 1 week
    B. 2 weeks
    C. 4 weeks
    D. 8 weeks

11. How many times can patients experiencing a recurrence of symptoms be re-treated with rifaximin?
    A. 1
    B. 2
    C. 3
    D. 4

12. Why was alosetron previously withdrawn from the market?
    A. Ischemic colitis
    B. Teratogenicity
    C. Presence of carcinogens
    D. Myocardial infarction

13. For which patient population was alosetron FDA-approved in 2002?
    A.Patients with mild IBS-D symptoms
    B. Men with IBS-D who have not responded to conventional therapy and have symptoms that are severe
    C. All patients ≤ 65 years old who have not responded to conventional therapy and have symptoms that are severe
    D. Women with IBS-D who have not responded to conventional therapy and have symptoms that are severe

14. What is the recommended starting dose for alosetron?
    A. 0.5 mg once daily
    B. 0.5 mg twice daily
    C. 1 mg twice daily
    D. 2 mg twice daily

15. Which IBS-D outcome was improved with the use of loperamide?
    A. Stool consistency
    B. Urgency
    C. Quality of life
    D. Bloating

16. Which drug is considered third-line treatment for IBS-D according to the AGA clinical decision support tool?
    A. Rifaximin
    B. Loperamide
    C. Alosetron
    D. Eluxadoline

Join a Committee

The Mississippi Pharmacists Association (MPhA) begins a new committee year each July. We invite you to join one or more committees. You can visit our website for committee information - mspharm.org/committees. Each committee addresses different topics relevant to MPhA business. Examples of topics discussed at each meeting could pertain to membership engagement (Membership), educational topics for conventions and journals (Education), ways to engage students and recent graduates (New Practitioner), and/or legislation (Government Affairs).

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FINANCIAL FORUM

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Retirement Blindspots

Some life and financial factors that can sometimes be overlooked.

We all have our "blue sky" visions of the way retirement should be, yet our futures may unfold in ways we do not predict. So, as you think about your "second act," you may want to consider some life and financial factors that can suddenly arise.

You may end up retiring earlier than you expect. If you leave the workforce at "full" retirement age (FRA), which is 67 for those born in 1960 and later, you may be eligible to claim "full" Social Security benefits. Working until 67 may be worthwhile because it will reduce your monthly Social Security benefits if you claim them between age 62 and your FRA.1 Now, do most Americans retire at 67? Not according to the annual survey from the Employee Benefit Research Institute (EBRI). In EBRI's 2020 Retirement Confidence Survey, 16% of pre-retirees expected to retire between ages 66-69, and 31% thought they would retire at age 70 or later. The reality is different. In surveying current retirees, EBRI found that only 6% had worked into their seventies. In fact, 70% percent of them had left work before age 65, and 33% had retired before age 60.2

You may see retirement as an extension of the present rather than the future. This is only natural, as we all live in the present – but the future will arrive. The costs you have to shoulder later in retirement may exceed those at the start of retirement. As you may be retired for 20 or 30 years, it is wise to take a long-term view of things.

You may have a health insurance gap. If you retire before age 65, what do you do about health coverage? You may shoulder 100% of the cost. Looking forward, you may need extended care, and it seems to get more expensive each year. Wealthy households may be able to "self-insure" against extended care, but many other households struggle. In Genworth's 2020 Cost of Care Survey, the median monthly cost of a semi-private room in a nursing home is $7,738. In California, it is $9,023; in Florida, $8,803.3 Suppose you become disabled or seriously ill, and working is out of the question. How do you make ends meet?

Age may catch up to you sooner rather than later. You may stay fit, active, and mentally sharp for decades to come, but if you become mentally or physically infirm, you need to find people to trust to manage your finances.

You could be alone one day. As anyone who has ever lived alone realizes, a single person does not simply live on 50% of a couple's income. Keeping up a house, or even a condo, can be tough when you are elderly. Driving can be a concern. If your spouse or partner is absent, will there be someone to help you in the future?

These are some of the blind spots that can surprise us in retirement. They may quickly affect our money and quality of life. If you age with an awareness of them, you may have the opportunity to manage the outcome better.

Citations
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Rx AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

COLLABORATIVE PRACTICE AGREEMENTS AND STATEWIDE PROTOCOLS

Pharmacists are increasingly given options to become more involved in patient care. Some of these options result in a pharmacist prescribing or initiating drug therapy. While the end result of these activities is very similar, legally, they are quite distinct. Collaborative Practice Agreements (CPA) are generally categorized as collaborative prescribing while Statewide Protocols (SP) are classified as autonomous prescribing. Let's explore the distinctions in more detail.

A CPA is a formal agreement between a pharmacist and a prescriber under which the pharmacist provides certain patient care functions, such as the initiation, monitoring, modifying, and/or discontinuing of drug therapy. Most states have laws that authorize CPAs. However, there is considerable variation in what practices, and to what extent, are allowed. The CPA must fall within the guidelines dictated by the law authorizing them. The CPA should be specific about the patient care functions delegated to the pharmacist and the guidelines for the pharmacist's performance of those functions. The nature of a CPA limits the pharmacist's intervention only to specific patients of the CPA's prescriber.

An SP is different in that it is not limited to a particular pharmacist or particular prescriber. An SP is issued by a state agency such as the Board of Pharmacy. The Board of Pharmacy may act in conjunction with other agencies, including the Board of Health. The SP is issued within the guidelines set by the state law or regulation that authorizes SPs. The SP authorizes any qualified pharmacist to provide the clinical service described in the SP. Most SPs authorize the pharmacist to prescribe and dispense a certain drug or class of drugs to fill the needs of the class of patients covered by the SP. Thus, an SP permits the pharmacist to intervene and provide services to a broader base of patients.

The training and education needed by the pharmacist to fulfill the clinical activities is provided in the law or regulation authorizing the CPA or SP. Any pharmacist wanting to expand the clinical services they offer should approach the addition of new clinical services methodically. What activities are authorized in your state for a CPA or an SP? It makes sense to proceed if your practice has a significant population of patients who could benefit from these additional services and you have the physical facilities to provide the services. These populations might be diabetics, asthmatics, or patients with other medical conditions. Once you have decided on a service to add to your practice, you need to examine whether you are competent and qualified to provide that service. If not, you should register for and obtain the needed training and certification. A pharmacist must comply with the procedures and recordkeeping required by the authorizing law or regulation.

As with any new activity, there will be an increase in your liability exposure. However, that exposure can be managed through an effective risk management program. Analyze the possible risks in advance of implementing the service and incorporate best practices in your procedures to mitigate those risks. A thorough understanding of the requirements and responsibilities under the CPA or SP is essential. Continuous monitoring of the quality of the services rendered is necessary to adjust procedures as situations change. Another component of a good risk management program is to have the proper insurance coverage in place. Consult with your insurance agent regarding coverage for your new service. No expansion of services is without risk, but effective policy and procedures can minimize those risks to a manageable level.

Keep your eyes and mind open when providing a new service. Research and proper preparation enables you to expand your practice within your risk tolerance benefiting both you and your patients.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

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