mississippi Pharmacist

Quarterly publication of the Mississippi Pharmacists Association | Winter 2022

Increasing Utilization of Evusheld™ for COVID-19 Pre-Exposure Prophylaxis
2.0 CE Hours

A Pharmacist's Guide to Brain Health Supplements
2.0 CE Hours

152nd Annual Convention & Trade Show

mississippi Pharmacist

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PRESIDENT'S MESSAGE

Dear MPhA Members,

I hope everyone has had a fantastic 2022! Though COVID-19 continues to have a lasting impact, it is apparent everywhere I go that life is returning to normal. It is refreshing to see faces again as mask mandates have been relaxed and as family and friends gather together to celebrate the holiday season.

Even as we enjoy resumption of activity, we remain vigilant and encourage the most vulnerable of our patients to take proper precautions. Outpatient visits for flu, RSV and other respiratory illnesses are surging in Mississippi and all other regions of the US according to CDC data. Pharmacy continues to serve on the front lines by providing treatments, administering vaccines and advising our communities on up to date treatment and prevention strategies.

In a landmark decision, the federal government called on pharmacists to prescribe Paxlovid for qualifying patients. While this is an important recognition of the value pharmacists provide, there remain barriers to adequate coverage of pharmacists' clinical services to test and treat these patients. MPhA is supporting national pharmacy organizations that are pushing for payment of these services and working locally to see pharmacists recognized as key providers in Mississippi.

In order to accomplish all of our goals related to Connection, Advocacy and Education, MPhA will continue to need pharmacy leaders across the state as active members. Please renew your membership today and thank you for joining with us to make 2023 another great year!

Merry Christmas and Happy New Year!!!

Tripp Dixon

Tripp Dixon, PharmD

MPhA President

President@mspharm.org

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- **Humana's 2022 Notice of Program Requirements** - Humana's Compliance Policy for Contracted Healthcare Providers explicitly states pharmacies must have a compliance program that meets the seven elements outlined by CMS, including written policies, procedures and standards of conduct.
- **PerformRx Pharmacy Compliance Attestation 2022/2023** - PerformRx requires attestations to the following: The pharmacy has implemented and maintains a compliance program that is consistent, at minimum, with applicable federal and state requirements, including, but not limited to the standards set forth in 42 CFR §423.504(b)(4)(vi) and other Centers for Medicare & Medicaid Services (CMS) guidance set forth in the Medicare Part D Prescription Drug Benefit Manual.
- While not public, **Express Scripts** and **Caremark** also have explicit language to require a compliance program. See Caremark's 2022 Provider Manual, Section 10.01.06 FWA program and Express Scripts 2022 Provider Manual with regards to maintaining a compliance program in accordance with CMS requirements.

Ensure you have all your compliance bases met so you can provide proof when requested for credentialing or audit. Don't have an FWA/HIPAA Compliance Program? Contact PAAS, info@paasnational.com or (608) 873-1342 and get started today!

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

INTERIM EXECUTIVE DIRECTOR'S LETTER

Greetings,

The holiday season allows us time to reflect on things for which we are most grateful; primarily, being in a great profession and providing healthcare across Mississippi are among them. One valuable lesson that the pandemic taught us is a crisis reinforces the value of great friendship. Over the last few years, our pharmacists and technicians launched into new roles across the industry. As we continue to transition into these new roles and excel at the challenges we face, we should strive to reinforce our professional connections as well. We learn from one another and stand stronger together. We, at MPhA, value our members, and we want to thank you all for your dedication to the profession. Without your loyalty and support, we would not be able to continuously provide valuable benefits and actively advance the pharmacy profession. We have come through a year filled with challenges and victories. How reassuring it has been to know that we can count on all of you; regardless of what challenges we face.

It has been extremely exciting getting to meet and spend time with pharmacy students at the University of Mississippi School of Pharmacy, both the Oxford and Jackson campuses, and the William Carey School of Pharmacy in Biloxi, Miss. I loved hearing the excitement you all share about the profession and your passion about your favorite football teams. Thank you Ole Miss and William Carey for allowing me to share the mission of MPhA. We value our partnerships and look forward future student events.

As for events:
We partnered with the Mississippi Public Health Institute (MsPHI) for the Last Chance Seminar. We had a great turnout and look forward to working with MsPHI more in the future.
We continue to work diligently on the 2023 MPhA Annual Convention & Trade Show to be held in Oxford, Miss. on June 8-10, 2023; we will be ready to start accepting registrations in January 2023.
A new year brings a new legislative session at the Mississippi State Capitol. MPhA lobbyist Mark Baker with Keystone Strategies, LLC is preparing for this lucrative session. With the help of our Government Affairs Committee, we are excited to bring back Capitol Day on January 17, 2023. Attendance numbers will be very limited because covid policies are still in place, but our voice will still be strong.

Lastly, I encourage you to serve on a committee – or two or three. Actively engaging with MPhA will help you develop your critical leadership skills and will forge those professional connections to help define your career path. I encourage you to give back to your profession.
Don't forget; all memberships expire on December 31, 2022. Go ahead and renew today to continue being a part of Voice of Pharmacy in Mississippi.

Sincerely,

Mona Arnold-McBride

Mona Arnold-McBride
Interim Executive Director

CONTINUING EDUCATION

Increasing Utilization of Evusheld™ for COVID-19 Pre-Exposure Prophylaxis

Sophie Durham, PharmD
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Mississippi State Department of Health Pharmacy

Introduction

The COVID-19 pandemic has placed immense stress on health care systems worldwide. As of the end of October 2022, it has been responsible for 1,066,351 deaths in the United States alone.[1]

Immunocompromised patients, regardless of their vaccination status, are at an increased risk for severe COVID-19-related outcomes, including intensive care unit (ICU) admission and death. Immunocompromised patients at the highest risk of in-hospital death include patients with a low CD4+ count, immunosuppressive therapy use, multiple myeloma, or solid organ transplant. The highest percentage of immunocompromised patients in the United States fall within the range of 50-69 years of age. These patients tend to have a higher prevalence of comorbidities, such as chronic lung disease, renal disease, and obesity, increasing their likelihood of severe COVID-19 and hospitalization.[2] Due to these factors, immunocompromised patients require additional protection from COVID-19 using multiple protection strategies, including nonpharmaceutical interventions, up-to-date vaccinations for them and their close contacts, early testing, and prophylactic and early antiviral treatment.[2]

Pharmacists have continued to provide essential services, such as medication dispensing for chronic and acute conditions, vaccinations, recommendations for over-the-counter medications, and medication management throughout the pandemic. Community pharmacies across the country employed social distancing strategies, including curbside pickup, larger refill quantities, and home delivery to safely maintain continuity of care.[3] Community pharmacists have been uniquely positioned to provide chronic care management and point-of-care testing to bridge gaps in care created by the pandemic. More than 10,000 pharmacies perform Clinical Laboratory Improvement Amendments (CLIA)-waived tests and point-of-care testing to detect new infections and monitor chronic conditions.3 Pharmacists have also been instrumental in the coordination and administration of COVID-19 tests and have increased the availability of COVID-19 vaccines to rural patients and patients of lower socioeconomic status through the wide-scale administration of vaccines.[3] Because patients with comorbid conditions at the highest risk of negative COVID-19 outcomes typically make frequent trips to the pharmacy to purchase prescriptions, community pharmacists have the opportunity to identify patients eligible to receive COVID-19 therapies.

What is Evusheld™?

Patients and health care providers alike may be wondering what preventative measures exist in addition to the COVID-19 vaccines. Evusheld™ (tixagevimab plus cilgavimab) is an investigational medicine available under the Emergency Use Authorization (EUA) used for pre-exposure prophylaxis (PrEP) for prevention of COVID-19 in adults and adolescents. In order to receive Evusheld™, patients must not have SARS-CoV-2 infection or have recently been exposed to an individual with SARS-CoV-2 infection and must be either moderately to severely immunocompromised with a potentially inadequate immune response to COVID-19 vaccination or not be able to be fully vaccinated with any available COVID-19 vaccines due to a history of a severe adverse reaction to a COVID-19 vaccine or any of its components.[4]

Tixagevimab and cilgavimab are recombinant human IgG1K monoclonal antibodies designed to block viral attachment and entry into human cells to neutralize the virus by binding to nonoverlapping epitopes of the spike protein receptor-binding domain of SARS-CoV-2, blocking attachment to the human ACE2 receptor.5 Evusheld™ is

administered as two separate intramuscular injections, one containing 300 mg of tixagevimab and one containing 300 mg of cilgavimab, given consecutively.[4]

The PROVENT trial assessed the safety and efficacy of Evusheld™ as pre-exposure prophylaxis by randomly assigning patients who had an increased risk of inadequate response to COVID-19 vaccination, patients at an increased risk of exposure to SARS-CoV-2, or both to receive either a single dose of Evusheld™ or placebo. Receiving Evusheld™ resulted in a 77% risk reduction of developing symptomatic COVID-19 infection when compared to placebo.[6]

It should be noted the dose used in the PROVENT Trial was 300 mg (150 mg of each of the two components).[6] Continuing surveillance of the virus and its susceptibility to these antibodies suggests the potential for decreased efficacy against the Omicron BA.4.6, BF.7, and BA.2.75 sublineages, each of which includes substitutions at spike protein 346. Nonclinical data and pharmacokinetic modeling suggest that activity against these subvariants may be retained for six months at drug concentrations achieved following administration of the updated recommended dose of 600 mg (300 mg of each of the two components).[5]

Providers should use caution when recommending Evusheld™ to patients with clinically significant bleeding disorders, patients with a history of cardiovascular events, patients with a severe allergic reaction to a COVID-19 vaccine, pregnant patients, and breastfeeding patients. Patients with a severe allergic reaction to a COVID-19 vaccine may be at an increased risk of an allergic reaction during or after an injection of Evusheld™ because this medication contains polysorbate 80, an ingredient also found in the Janssen COVID-19 vaccine and is similar to polyethylene glycol (PEG) found in the Pfizer and Moderna COVID-19 vaccines.[5] In patients with a severe allergic reaction to a COVID-19 vaccine, clinicians should consider consulting an allergist-immunologist prior to administering Evusheld™. Patients receiving Evusheld™ should be monitored for allergic reactions during and one hour after receiving the injection.[5] A higher proportion of patients with a prior history of cardiovascular disease at baseline who received Evusheld™ had a cardiac serious adverse event during the PROVENT trial, with one cardiovascular death reported in the treatment group.[6] Because of this finding, patients with a history of heart attack or stroke should be closely monitored for signs and symptoms of cardiac events after administration. This injection is contraindicated in patients with previous severe hypersensitivity reactions to Evusheld™. The most common side effects of the injection include pain, bruising of the skin, soreness, swelling, and possible bleeding or infection at the injection site.[5]

Who is eligible to receive Evusheld™?

Moderately to severely immunocompromised patients due to a medical condition or receipt of immunosuppressive treatment who may not mount an adequate immune response to COVID-19 vaccination or patients who cannot tolerate COVID-19 vaccines due to a history of a severe adverse reaction are authorized to receive Evusheld™. These patients must not be currently infected with SARS-CoV-2 or have been recently exposed to an individual with SARS-CoV-2 as this medication is authorized as pre-exposure prophylaxis only. Use is authorized in patients 12 years of age and older who weigh at least 88 pounds.[5] Immunocompromising conditions that qualify patients to receive Evusheld™ include but are not limited to the patient populations included in Figure 1. Evusheld™ is not authorized for use in individuals for treatment of COVID-19 or for post-exposure prophylaxis of COVID-19. The STORM CHASER trial enrolled adult patients who had been exposed to an individual with a laboratory confirmed SARS-CoV-2 infection within the past 8 days to determine the effectiveness of Evusheld™

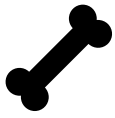
Immunocompromised Patient Populations Eligible for Evusheld™			
	Are on active treatment for solid tumors or blood cancer		Have moderate or severe primary immunodeficiency
	Received an organ transplant and are taking medicine to suppress your immune system		Have advanced or untreated HIV infection
	Received a stem cell transplant and are within 2 years of transplant or taking medicine to suppress your immune system		Are on active treatment with high-dose corticosteroids or other medicines that may suppress your immune system

Figure 1

as post-exposure prophylaxis.[7] Individuals who had previously received a COVID-19 vaccine, had symptoms consistent with COVID-19, or had a known prior SARS-CoV-2 infection were not included in this study. The STORM CHASER study did not demonstrate benefit for Evusheld™ in preventing symptomatic COVID-19 after known exposure.[7] Pre-exposure prophylaxis with Evusheld™ is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Patients should wait at least 2 weeks after receiving a COVID-19 vaccine to use Evusheld™ because it is possible that Evusheld™ may reduce the body's immune response to the COVID-19 vaccine. For patients seeking ongoing protection, additional doses of Evusheld™ are required every 6 months to protect the patient against new variants.[5]

Where is Evusheld™ available?

Evusheld™ is available to patients at certain cancer and transplant centers across Mississippi. The Mississippi State Department of Health has compiled a list of participating health care facilities in Mississippi organized by county, provider name, address, city, and zip code and can be accessed using the QR code provided in Figure 2. Evusheld™ availability in Mississippi is illustrated in Figure 3. The Administration for Strategic Preparedness and Response (ASPR) provides a national list of locations providing COVID-19 therapeutics and is available using the QR code provided in Figure 4.

What can pharmacists do?

Community pharmacists have consistent face-to-face interactions with patients with chronic or immunocompromising conditions at prescription pick up. More than 90% of Americans live within five miles of a community pharmacy, making pharmacists one of the most accessible health care providers.[3] During medication dispensing or COVID-19 vaccine administration, pharmacists have the opportunity to educate patients on COVID-19 prevention strategies, such as Evusheld™. Pharmacists are vital to linking these vulnerable patients to care. Using the location lists published by the Mississippi State Department of Health and/or ASPR, pharmacists can refer patients to participating health care facilities to receive Evusheld™ injections for increased protection against COVID-19 infection. While these roles can place more pressure on pharmacy personnel, especially those on the front line, the potential benefits to patient could literally be lifesaving. Although pharmacists cannot currently administer Evusheld™, we have seen pharmacists' roles expand with administration of REGEN-COV in the pharmacy. For now, Evusheld™ will continue to be administered in health care providers' offices under the supervision of a health care provider with appropriate medical support to manage severe hypersensitivity reactions; however, pharmacists should always be prepared to assume public health roles.

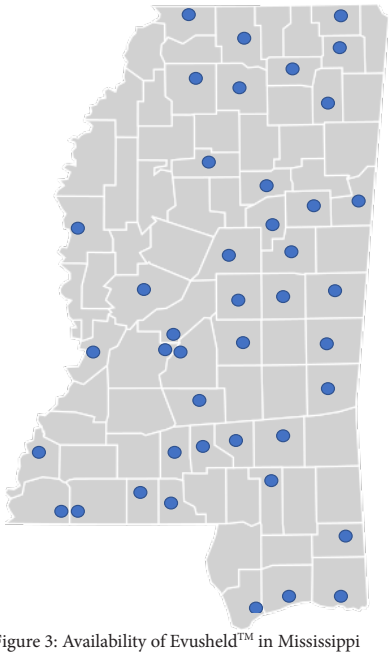


Figure 3: Availability of Evusheld™ in Mississippi

Figure 2

Figure 4

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CONTINUING EDUCATION ARTICLE QUESTIONS

CE Approval #011-018-022-001 for 2.0 clock hours. CE Credits are valid through July 2024.

Increasing Utilization of Evusheld™ for COVID-19 Pre-Exposure Prophylaxis

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.

Print name, phone number, and email:

To mail your quiz, include a self-addressed and stamped envelope and mail to:
MPhA, PO Box 16861, Jackson, MS 39236

Name _____

Phone _____ Email _____

1. Evusheld™ is currently recommended at which dose?
   a. 150 mg of tixagevimab plus 150 mg of cilgavimab
   b. 150 mg of tixagevimab plus 300 mg of cilgavimab
   c. 300 mg of tixagevimab plus 150 mg of cilgavimab
   d. 300 mg of tixagevimab plus 300 mg of cilgavimab

2. Of the following, for which patient group is Evusheld™ indicated?
   a. Patients aged 6 years and older who might not have an adequate immune response to the COVID-19 vaccination and have no known exposure to SARS-CoV-2
   b. Patients who have been exposed to a patient with a laboratory-confirmed case of SARS-CoV-2 within the last 8 days
   c. Moderately to severely immunocompromised patients aged 12 years and older who weigh at least 88 pounds and have not been exposed to SARS-CoV-2
   d. Patients with a current SARS-CoV-2 infection

3. Which condition by itself qualifies a patient to receive Evusheld™?
   a. Diabetes
   b. Advanced HIV infection
   c. Hypertension
   d. Asthma

4. Which trial showed a lack of efficacy as post-exposure prophylaxis using Evusheld™?
   a. EPIC-HR
   b. TACKLE
   c. STORM CHASER
   d. PROVENT

5. Which ingredient found in Evusheld™ and COVID-19 vaccinations can lead to a severe allergic reaction?
   a. Polysorbate 80
   b. L-histidine
   c. Latex
   d. Sucrose

6. What is the recommended timing interval between receiving a COVID-19 vaccination and Evusheld™?
   a. 1 week after COVID-19 vaccination
   b. 2 weeks after COVID-19 vaccination
   c. 3 weeks after COVID-19 vaccination
   d. 4 weeks after COVID-19 vaccination

7. Which preexisting condition has shown an increased risk of serious adverse events in patients treated with Evusheld™?
   a. Solid organ transplant
   b. Chemotherapy
   c. High-dose corticosteroids
   d. Stroke

8. Which age range encompasses the highest number of immunocompromised patients?
   a. 2-years-old to 19 years-old
   b. 20-years-old to 39-years-old
   c. 50-years-old to 69-years-old
   d. >70-years-old

9. How often should patients seek additional doses of Evusheld™ for continued protection?
   a. Every month
   b. Every 3 months
   c. Every 6 months
   d. Every 1 year

10. What is the most common adverse reaction associated with Evusheld™?

a. Swelling at the injection site
b. Nausea
c. Diarrhea
d. Hypotension

11. Where can you find a list of health care facilities that administer Evusheld™ in Mississippi?

a. FDA website
b. CDC website
c. AstraZeneca's Evusheld™ website
d. Mississippi State Department of Health website

Mississippi Pharmacists Association

2023 Events

*Dates are TBD

Capitol Day
January 17, 2023

Mid-Winter
February 5 & 19, 2023

152nd Annual Convention
June 8-10, 2023

Spring District Meetings
*March 2023

Consultant Seminar
*September 2023

Fall District Meetings
*October 2023

New Practitioner's Social
*April & November 2023

Last Chance Seminar
*December 2023

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CONTINUING EDUCATION

A Pharmacist's Guide to Brain Health Supplements

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The authors gratefully acknowledge support from the National Center for National Products Research at the University of Mississippi for development of this continuing education article.

Learning Objectives

1. Identify ingredients commonly found in brain health supplement products.
2. Recognize the variability in availability, cost, and dosing of brain health supplements.
3. Recall the way in which brain health supplements are marketed and regulated.
4. Identify drug interactions and adverse events that may be associated with brain health supplements.
5. Provide appropriate counseling points for patients considering brain health supplements.

Brain health dietary supplements are products often used to improve memory and cognition. The target market for these products is an aging population. A recent survey by American Association of Retired Persons (AARP) shows, "... more than a quarter of Americans ages 50 to 73 are regularly taking supplements for their brain health, and that this figure rises to 36 percent for those over 74."[1] These statistics show that not only are these supplements reaching their target market, but they are doing so with a very high success rate. Brain supplement sales are expected to reach $5.8 billion by 2023.[1]

It should be noted that brain health supplements do not go through the same Food and Drug Administration (FDA) drug approval process as prescription or over-the-counter medications because they are considered dietary supplements by the regulators. Therefore, like other dietary supplements, brain health supplements generally do not have FDA-approved indications for their use. As a result, marketers of brain health supplements are limited to making general structure and function claims about how brain function can be supported. These generally include supporting focus, memory, learning, accuracy, mood, and concentration.

During the summer of 2022, student pharmacist researchers at the University of Mississippi School of Pharmacy conducted a non-exhaustive market evaluation of brain health supplements using an online search method. Their evaluation resulted in the identification of 34 unique dietary supplement products marketed for brain health (Table 1). These products vary in where they may be purchased, how much they cost, how they are to be taken, and the ingredients they include. This recent unpublished market evaluation is considered non-exhaustive, as other research has shown there are as many as 650 unique dietary supplement products containing 72 "frequently used" ingredients marketed for brain heath and cognitive enhancement documented in the literature.[2]

Overview of Brain Health Supplements

Ingredients. There are a multitude of brain health supplements available on the market, but many of them contain various combinations of similar ingredients. A detailed appendix that lists ingredients in each of the 34 products identified by the unpublished market evaluation can be found at https://tinyurl.com/2nc2ryd5. Some of the most common ingredients are ginkgo extract,

Table 1: Brain Health Supplement Products Identified in 2022 Market Evaluation

Brain Supplement Product	Cost	Amount	Recommended dose
Advanced Brain (Procera)	$59.95 (Procera), $59.95 (Amazon), $59.99 (GNC)	60	Take 2 cap QD
Ageless Brain (Organixx)	$37.14 (Amazon), $54.95 (Organixx), $49.00 (PureHealth), $49.00 (walmart)	60	2 cap QD with 8 fluid ounces water
Alpha Brain (Onnit)	$71.96 (Amazon), $34.99 (30 count - CVS), $63.99 (Vitamin Shoppe), $89.00 (Walmart)	90	2 capsules daily w light meal
Amplified Focus (GNC)	$39.99 (GNC)	60	Take 2 QD
Arms Race Clarity	$49.99 (GNC), $49.99 (Amazon), $44.99 (Nutrition Corners)	112	2 capsules BID on empty stomach
Beyond Raw Chemistry Labs Nootropic	$34.99 (GNC), $34.99 (Amazon)	30	Mix one scoop with 8 ounces water
Botonic Choice Memory	$19.99 (Botonic Choice), $19.99 (Walmart)	30	1 cap QD with meal
Brain Awake Irwin Naturals	$16.19 (Irwin Naturals), $19.99 (Walgreens), $18.79 (Target), $18.69 (Amazon)	60	take 3 cap QD with meal
Brain Health (Garden of Life)	$23.93 (Amazon), $25.19 (iHerb), $25.19 (Walmart)	60	Tale 2 tablets daily with food
Brain Health Formula (GNC)	$39.99 (GNC), $39.99 (Amazon)	60	take 2 QD with meal
Brain Pill	$69.95 (Leading Edge Health)	60	1 capsule am 1 capsule afternoon w water
Brain Strong Memory	$16.87 (walmart), $16.24 (iHerb), $16.99 (Walgreens),	30	1 tab QD with meal
Cocoavia Memory+	$49.99 (Amazon), $44.99 (CocoaVia), $46.99 (Walmart)	90	3 QD with meal
Cognium (Natrol)	$19.47 (Amazon), $23.29 (Walgreens), $19.97 (Walmart)	60	1 tab am & 1 tab pm
Dopamine Brain Food (Natural Sacks)	$39.99 (GNC), $34.95 (Natural Sack), $39.95 (Pharmaca), $42.99 (Vitamin Shoppe), $39.89 (Walmart)	60	take 2-3 cap in morning PRN not exceed 6 cap
Focus Factor	$24.99 (FOCUS Website), $25.19 (Amazon), $34.99 (Walmart)	180	4-8 tablets a day
Focus Formula	$19.99 (Amazon), $24.99 (120ct-GNC)	60	take 2 tab QD with meal
ForeBrain (Force Factor)	$25.99 (Walgreens), $19.99 (iHerb), $29.99 (60ct- Amazon), $23.99 (CVS), $24.99 (GNC)	30	1 cap QD
Genius Mushrooms	$21.99 (Target), $23.99 (Amazon), $24.99 (CVS), $22.99 (Vitamin Shoppe)	90	3 tablets a day
Ginkgo Biloba (Nature's Bounty)	$17.49 (Walgreens), $18.46 (Amazon), $12.38 (Walmart), $20.99 (CVS), $15.49 (Rite-Aid)	100	1 tablet daily with food
Himalaya Herbal	$17.99 (Walgreens), $15.96 (Walmart), $15.49 (Amazon), $20.99 (Vitamin Shoppe), $18.99 (Himalaya)	60	1 capsule QD AC
LumUltra	$59.97 (LumUltra)	60	take 2 cap QD with meal
Mason Natural Ginkgo Biloba	$12.42 (Amazon), $10.84 (iHerb), $21.48 (Walmart)	180	1 cap QD with meal
Memotenz	$19.95 (Walmart), $44.95 (60 count - Amazon)	30	1 capsule daily
Mind Lab Pro	$93.99 (Walmart), $82.99 (Amazon)	60	2 capsules QD
Neuriva	$34.99 (GNC), $44.79 (CVS), $27.97 (Amazon), $29.99 (Target), $29.97 (Walmart)	30	1 capsule daily
Neuronol	$49 (Pharmagetics)	60	2 capsules daily 20-30 minutes before a meal
NeuroSphere (NDS Nutrition)	$69.99 (GNC), $56.59 (Amazon), $62.99 (Walmart)	90	3 cap QD with 6-8 fluid ounces water and meal
Nordic Naturals Omega Focus	$49.99 (GNC), $49.95 (Nordic Naturals), $42.46 (Walmart), $42.46 (iHerb), $42.46 (Amazon)	60	take 2 cap QD with meal
Olympian Lab Vinpocertine	$17.49 (OlympianLab), $8.99 (Walgreens), $9.85 (HerbPro)	60	1 cap QD
OptiMind	$26.96 (Amazon), $29.99 (CVS)	32	1-2 capsules am with water
Prevagen	$39.92 (Walmart), $31.95 (Amazon), $39.99 (Walgreens)	30	1 capsule in am
Qualia Mind	$37.99 (Vitamin Shoppe), $125.10 (154 count - Amazon), $36.19 (Walmart)	35	take 7 cap in morning on empty stomach
RediMind	$52.43 (Walmart), $39.95 (Amazon)	30	1 capsule QD or BID as directed by physician

Vitamin B6, Vitamin B12, Phosphatidylserine, Bacopa extract, and L-tyrosine. Each of these are commonly marketed supplements individually, and all have been claimed to have mental benefits. Ginkgo is often used as an aid to memory. While benefits have been seen in patients with mild cognitive impairment or dementia, memory benefit has not been established in healthy individuals.[3] ***Vitamins B6 and B12*** are beneficial for allowing the body to process energy from food.[4] Evidence suggests that these vitamins slow cognitive decline, but their role in maintaining cognitive function is inconclusive.[5,6] ***Phosphatidylserine*** is a phospholipid that is largely present in the cell membranes of the brain and nervous system. Loss of this phospholipid throughout age leads to cognitive decline and Alzheimer's in elderly populations,[7] thus often used as an ingredient in brain health supplements. ***Bacopa extract*** has shown efficacy in improving memory free recall, but other cognitive benefits of Bacopa are currently inconclusive.[8] L-tyrosine, a nonessential amino acid that is an important component of neurotransmitter production, may improve mental performance in stressful situations. Studies have supported improvement in working memory for women[9] and also cognitive flexibility.[10]

Availability. In conducting a market evaluation of brain health supplements, it was found that a majority of these products can be found at pharmacies, such as CVS and Walgreens, health and wellness stores, such as GNC, on manufacturer websites, and even at grocery stores, like Walmart and Kroger. These products are readily accessible to consumers, as they can be purchased at many stores, possibly leading to their increased popularity. Table 1 includes a non-exhaustive list of where the 34 identified brain health supplement products can be purchased.

Recommended dosing. Table 1 includes manufacturer-suggested doses for each of the 34 identified brain health supplement products, ranging from 1-8 tablets or capsules a day. Brain health supplements may also be available as powders. Some brain health supplement products recommend a once daily dose, whereas others suggest twice-a-day dosing. Additionally, manufacturer recommendations vary by whether the products should be taken with a meal or on an empty stomach, and specific amounts of water with which the supplements should be taken. Pharmacists should be sensitive to the fact that

these various dosing regimens may not only be challenging for patients, but could also contribute to compromised efficacy seen with these products, as patients may have difficulty achieving the correct dosing.

Brain health supplement cost. As seen in Table 1, the identified brain health supplement products range in price from $12 to $94, with the majority of packages containing a one month supply. Pharmacists should be aware that the cost of these products may be misunderstood by patients, because the majority of the suggested doses require 2-3 tablets or capsules a day. For example, consumers may believe they are spending around $30 for a 6 month supply (180 tablets) of Focus Factor, when in reality, the 180 tablet bottle would only be a 1 month supply if following the recommended dosing of 4-8 tablets a day, making the product $30 for a 1 month supply.

Marketing and regulation. Dietary supplements (including the brain health supplements described in this article), are not regulated by the FDA in the same manner as prescription and over-the-counter drugs. This is due to passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, which exempts supplements being legally defined drugs. This means even though supplements, like drugs, could affect the structure and function of the body per the FDA drug definition, they do not have to regulated like FDA-approved drugs. Because of this, there is no guarantee that the ingredients indicated on the label of these products is a true representation of what they contain. The FDA warns consumers:

"Dietary supplements are regulated by the FDA as food, not as drugs. However, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. For these reasons, it is important to consult with a health care professional before using any dietary supplement."[11]

This is not to suggest that all dietary supplement products are intentionally or unintentionally mislabeled. Their labeling is simply not approved by the FDA. As part of DSHEA, manufacturers of supplement products may not indicate on their labeling that their product is intended to prevent, treat, cure, mitigate, or diagnosis disease. In fact, it is quite the opposite, manufactures must include the statement, *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease,"* when making structure/function claims about their product. DSHEA and the FDA allow dietary supplement manufacturers to make general structure and function claims about their products.[12] These will often be vaguely indicted, as to avoid making illegal drug claims. As such, brain supplement products will often claim to "boost," or "support" brain function, or to provide "clarity".

With regard to claims, a recent and uniquely designed study was conducted by a collaborative of the Consortium for Health and Military Performance, Henry M. Jackson Foundation for the Advancement of Military Medicine and the National Center for Natural Products Research at the University of Mississippi. This scoping review was conducted to identify brain health supplements, and a content analysis subsequently conducted to analyze their claims, followed by a physical quality analysis of the actual product to identify actual ingredients. Of the twelve products ultimately analyzed at the University of Mississippi, eight had at least one ingredient listed on their label that was not found in the actual product. Compounds not listed on the label were found in ten of the twelve products. The authors subsequently warned of the adulteration and misbranding found in brain health supplements.[2]

Although the FDA does not approve dietary supplements before marketing, some safeguards do still remain. A premarket safety notification must be submitted to the FDA by the manufacturer at 75 days before marketing a supplement if it contains a substance that was not marketed prior to the passage of DSHEA. Dietary supplement production facilities are required to comply with good manufacturing practices to assure safety. These facilities are inspected by the FDA and adverse event reporting is monitored (known adverse events must be reported by supplement manufacturers). When public concern is raised about a particular supplement, the FDA can intervene to protect the public in the form of product seizures and banning products, if voluntary action is not taken by the manufacturer

producing the problematic supplement.[13]

Clinical Considerations for Brain Health Supplements

Drug Interactions. Because brain supplements often have pharmacologic activity, some of their components can lead to drug interactions. Components such as St. John's wort, ginkgo biloba, bacopa, and others can cause interactions without consumers realizing the effects it is having on their medication(s). The FDA reported, "drugs for HIV/AIDS, heart disease, depression, treatments for organ transplants, and birth control pills are less effective when taken with St. John's wort" and goes on to state that, "warfarin (a prescription blood thinner), ginkgo biloba (an herbal supplement), aspirin, and vitamin E (a supplement) can each thin the blood. Taking any of these products together may increase the potential for internal bleeding or stroke."[14] While these statements by the FDA seem to be stated with more certainty than is warranted, the concept of the potential for drug interactions is an important consideration. It has been further reported that bacopa interacts with antidepressants potentially causing serotonin syndrome, a potentially life threatening condition.[15] Patients should be advised to consult their doctor and pharmacist before starting any new dietary supplement to avoid potentially dangerous interactions with their current medications.

Adverse Events. As with other supplements, patients taking brain health supplements may also not fully realize their adverse event potential. This can be particularly dangerous since dietary supplement packaging is not required to list the potential adverse effects. Also of concern is the lack of standards for maximum pill size (a swallowing risk for the elderly).[16] According to the FDA there are multiple adverse effects that may occur from using dietary supplements. Some of these adverse effects may occur immediately, over time, or not at all. These adverse effects may range from mild to life threatening. A list of potential adverse events associated with dietary supplements as cited by the FDA can be found in Table 2.[17]

Table 2: Potential Adverse Events Associated with Dietary Supplements14

Itching, rash, hives, or wheezing
Fatigue or appetite loss
Severe, persistent nausea, vomiting, diarrhea, or abdominal pain
Difficulty urinating, decreased urination, or dark urine
Marked mood, cognitive, or behavioral changes
Severe joint or muscle pain
Yellowing of the skin or eyes
Abnormal bleeding from the nose or gums
Blood in urine, stool, or vomit
Throat, lip, or tongue swelling
Low blood pressure, fainting, chest pain, or shortness of breath
Stroke (slurred speech, one-sided weakness of face, arm, leg, or blurry/loss of vision)

Clinical Evidence for Benefit. Clinical evidence supporting use of brain supplements is most commonly available for individual ingredients in these products.[5-8] There is less evidence available for the proprietary combinations of these individual products. While many supplement manufacturers do claim scientific evidence of improvements in focus, memory, learning, accuracy, mood, and concentration, the studies are often company-sponsored and lack description of methodological detail when disseminating for marketing purposes.[18]

Pharmacist Counseling Points

As with all dietary supplements that are minimally regulated, pharmacists should exercise caution in their recommendations of brain health supplements to patients, and limit recommendations to those substances with which they are familiar and trust, given that reliable evidence for the safety and efficacy of brain health supplements is still emerging. It is important that pharmacists ensure that none of the ingredients of patients' preferred brain health supplements interact with their prescription medications. Patients should be counseled on how to properly take the supplements, should they choose to, and to look for signs of common adverse effects, such as allergic reactions. Pharmacists may also want to counsel their patients on the cost of brain health supplements concomitantly with dosing recommendations, so that patients fully understand the total cost of their supplementation.

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A Pharmacist's Guide to Brain Health Supplements

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1. Of the following, which most closely reflects to percentage of Americans aged 50-73 reported to take dietary supplements for brain health as reported by the AARP survey?
    a. 5%
    b. 10%
    c. 25%
    d. 50%

2. What proposed benefits are generally marketed by dietary supplements?
    a. Supporting focus
    b. Supporting motivation
    c. Supporting mental health
    d. Supporting happiness

3. Which of the following is a common purchase location for brain health dietary supplements?
    a. Pharmacies
    b. Doctor's offices
    c. Co-op stores
    d. Urgent care clinics

4. Which of the following is a common addition to brain health dietary supplements due to claims of memory benefit?
    a. Garlic
    b. Insulin
    c. Ginkgo (biloba) extract
    d. Gotu kola

5. Research has shown there are as many as _____ unique dietary supplement products containing _____ "frequently used" ingredients marketed for brain heath and cognitive enhancement.
    a. 72; 34
    b. 72; 560
    c. 650; 34
    d. 650; 72

6. How does the FDA regulate supplements?
    a. The same way as prescription medications
    b. The same way as over-the-counter medications
    c. The same way as food
    d. The same was as cosmetics

7. Which of the following is a suggested counseling point for patients considering purchasing brain health dietary supplements?
    a. Pharmacists should discourage the use of these products
    b. Pharmacists should encourage all of their patients to use these products
    c.Pharmacists should recommend that patients take these supplements as needed
    d. Pharmacists should counsel on the possible interactions and cost concerns with these products

8. Of twelve brain health supplements analyzed at the University of Mississippi as part of a collaborative with the Consortium for Health and Military Performance and the Henry M. Jackson Foundation for the Advancement of Military Medicine, how many supplements had at least one ingredient listed on their label that was not found in the actual product?
    a. 4
    b. 5
    c. 8
    d. 10

9. Which of the following adverse events does the FDA warn consumers about with use of dietary supplements?
    a. Kidney Failure
    b. Fatigue
    c. Hypertension
    d. Constipation

10. Of the following, which is the most significant concern for patients taking brain health dietary supplements?
    a. Lack of places to find brain health supplements
    b. Lack of enough brain health supplement product options to choose from
    c. Cheap prices being reflective of poor quality
    d. Possibility of adverse reactions

11. Of the following, which resource should be at the forefront of patient's decision to take brain health supplements?
    a. A pharmacist
    b. TikTok
    c. A television commercial
    d. Amazon

12. Which of the following brain health supplements can thin the blood?
    a. Warfarin
    b. Aspirin
    c. Ginkgo Biloba
    d. Ibuprofen

13. Of the following, which type of medication is most likely to have a decrease in efficacy when taken with St. John's wort?
    a. Birth control pills
    b. Opioids
    c. Amphetamines
    d. Inhalers

14. What is something that patients should do before starting brain health supplements?
    a. Stop their prescription medications
    b. Consult a health care professional
    c. Tell their family
    d. Fast for 24 hours

15. Which of the following laws exempt dietary supplements from being legally defined as a drug?
    a. ACA
    b. FDCA
    c. DSHEA
    d. CSA

16. Which of the following would be a legal structure/function claim for marketing a dietary substance for brain health?
    a. Treats memory loss
    b. Prevents Alzheimer's
    c. Cures dementia
    d. Supports focus

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Problem:

Adverse drug events are the fourth leading cause of death in the U.S.[1, 2,3] The number of older adults taking five or more drugs tripled from 1994 to 2014. If the trend continues, medication overload could cause at least 4.6 million hospitalizations between 2020 and 2030, costing families a staggering $62 billion[4].
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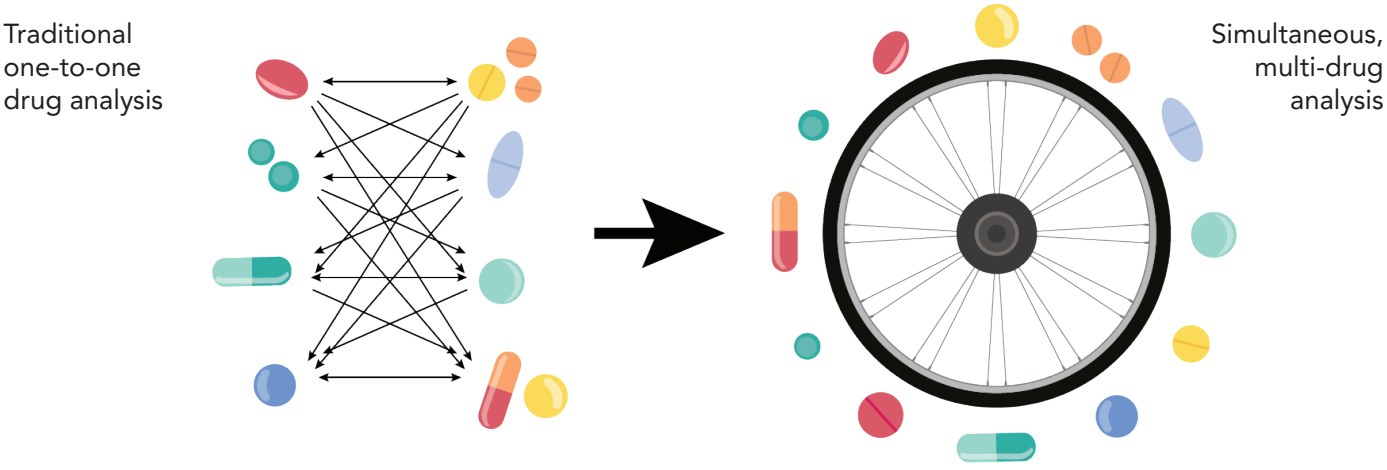

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