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## **Controversial New Alzheimer's Drug: What to Know**

*By Kathleen Doheny*

**T**he recent FDA's approval of a new drug to treat Alzheimer's disease was met with both praise and criticism. As the first Alzheimer's drug approved since 2003, advocates applaud the decision. Critics say the approval was based on inadequate proof that the drug works and balk at the price tag of \$56,000 a year.

Here's what else you need to know.

### **How the Drug Works**

The new drug, aducanumab (Aduhelm), is a monoclonal antibody

that reduces the buildup of amyloid plaques in the brain. These plaques, as well as tangles known as tau and other changes in the brain, are what lead to memory loss and eventually the inability to perform simple tasks like dressing oneself.

The drug is given intravenously once a month.

### **The Price**

According to Biogen, the annual price of the infusions is about \$56,000. People won't likely be paying that

amount, says Lon Schneider, MD, director of the California Alzheimer Disease Center. Within days, Biogen promised multiple ways to help patients access the drug. The company will provide service coordinators to provide one-on-one support, it says.

Specifics about how Medicare and insurance plans will cover the drug will take some time to work out, Schneider says. But he says even people without insurance will likely be able to negotiate down the price.

A spokesperson for the Centers for Medicare and Medicaid Services said, “CMS is reviewing the FDA’s decision regarding aducanumab and will have more information soon.”

### **Best Patients? Advice for Families**

The new drug is certainly not meant for everyone with Alzheimer’s, says Julia Biernot, MD, a behavioral neurologist at the University of Maryland School of Medicine, Baltimore. “It’s important to know that it is most likely going to be indicated in patients who have mild Alzheimer’s disease or mild cognitive impairment, as opposed to more advanced disease. And there may be potential side effects that need to be discussed with patients and their families.”

The most common, according to Biogen, is a condition known as ARIA – amyloid-related imaging abnormalities, found in 41% of patients in one study. These problems include temporary swelling in the brain and small areas of bleeding.

While she calls the approval “an exciting development overall,” Biernot also cautions families that the treatment would probably be needed indefinitely.

“There isn’t a profile for the best patient,” Schneider says. The clinical studies enrolled people with mild cognitive impairment or MCI, a precursor

to Alzheimer’s, and with mild Alzheimer’s. “That’s the group in which the drug has been tested,” he says. “Not necessarily tested and shown to be effective, but tested.”

“I think people who come with symptoms, with MCI due to Alzheimer’s or with mild Alzheimer’s, who wish to try the monthly infusions for a year and a half [the schedule used in the trials], we would be happy to support them,” Schneider says. He stresses, however:

“Families need to do their own research and talk to their doctor.”

**The approval came as a surprise to many, as the FDA’s own advisory committee last November voted 8 to 1 against approving the drug, citing lack of strong evidence that the drug works. One member of the advisory board resigned over the FDA decision, STAT reported.**

### **FDA’s Accelerated Approval**

The FDA granted accelerated approval based on clinical trials that showed the reduction of plaque in the brain in those given the drug compared to those in the control or placebo group. The approval came after the FDA evaluated three separate studies of the drug involving nearly 3,500 patients.

The approval came as a surprise to many, as the FDA’s own advisory committee last November voted 8 to 1 against approving the drug, citing lack of strong evidence that the drug works. One member of the advisory board resigned over the FDA decision, STAT reported.

“The FDA approved this based on the antibody reducing amyloid plaques,” Schneider says. Reduction of the plaque, however, does not prove that there is a clinical benefit, such as preventing deterioration of memory, he says.

The companies marketing the drug, Biogen and Eisai, must do ongoing studies to verify that the drug has a clinical benefit. If this new trial does not show a benefit, the FDA can withdraw approval.

Another expert, James E. Galvin, MD, professor of neurology at the University of Miami Miller School of Medicine, compares the approval of the new drug based on its ability to remove plaque to a cancer drug approved because it can shrink a tumor. “If you have a cancer drug that shrinks a tumor, you have proof that it

works, it engages its target. That may or may not mean a clinical effect, or a small clinical effect.” Galvin was an investigator on one of the clinical trials for aducanumab and is an advisor to Biogen.

Like other experts, Galvin says the aducanumab approval may pave the way for future Alzheimer’s drugs being approved that are even more effective. “The first medicine approved is not necessarily always the best.”

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*WebMD Health News*



## Protecting your Patient’s Aging Skin

**T**he normal changes of aging mean that elderly patients are more prone to interruptions in skin integrity, such as pressure ulcers, than younger patients. Elderly patients also need more time to heal, and their skin problems can lead to additional medical complications. By examining an elderly

patient’s skin frequently and documenting and treating problem areas, you can help head off problems.

### **Changes related to aging**

Here are some of the changes that put older patients at greater risk for skin breakdown:

- **Thinner, more fragile skin.** Dermal thickness decreases 20%, and the turnover rate for the epidermis falls by 50%. The skin becomes almost translucent and provides less protection against invading organisms. Medication absorption through the skin may be increased, and the skin's ability to synthesize vitamin D is reduced.
- **Reduced dermal vascularity contributes to the skin's pale appearance.** Because fewer nutrients reach the skin and fewer waste products are removed, the skin's ability to heal is also impaired. In an elderly person with circulation problems, decreased hemoglobin and hematocrit levels can further compromise oxygen and nutrient delivery to the skin. Because blood vessels become more fragile, the elderly bruise easily. Someone taking anticoagulant medication is at even greater risk for bruising.
- **Decreased collagen production.** Collagen, which makes up about 70% of skin's dry weight, is the principal structural body protein. Collagen production decreases with aging—by about 1% per year—and the collagen that is produced is thicker and less flexible. Skin has less give, making the elderly more susceptible to tear-type injuries.
- **Less adhesion between skin layers.** In elderly people, the papillae that keep the dermis and epidermis together (dermoepidermal junction) flatten out, resulting in less adhesion between the two layers of skin. This makes the skin more susceptible to injury from shear and friction, another reason why tear injuries are so common in the elderly.
- **Fat is redistributed to the abdomen and thighs,** so bony areas such as the sacrum have less cushioning.
- **Reduced ability to feel touch or pressure.** Aging is associated with a decrease in sensory percep-

tion, increasing the likelihood of an ischemic episode from sitting or lying too long in one position. For example, a younger adult normally shifts his body weight at least every 15 minutes, even during sleep. But because of sensory changes, limitations in movement, and the effects of some medications (especially sedative effects), an elderly person may not feel the need to shift his weight often enough, leading to skin ischemia and breakdown.

- **Decreased sweat gland function.** Less sweating contributes to overly dry skin that cracks if not moisturized. These cracks can become portals of entry for bacteria and lead to further skin breakdown.

### Helpful interventions

Here are some ways to ward off skin breakdown:

- **Assess the patient's skin regularly—from head to toe.** Look at the patient's hair distribution: Hair loss may indicate peripheral arterial disease. Also check skin color, temperature, texture, and turgor.
- **Check the patient's feet daily, even if the patient doesn't have diabetes.** Although heel and foot ulcers are common in patients with diabetes, they're also a risk for anyone with decreased circulation and sensation.
- **Turn and reposition the patient as needed.** A traditional 2-hour turning schedule may not be frequent enough for an elderly patient, so tailor the schedule to your patient's needs. Turning him every 90 minutes may be more appropriate while he's in bed; when he's sitting in a chair, reposition him every hour.
- **Keep skin dry.** Excessive, prolonged wetness leads to maceration, increasing the effects of friction and shear on already fragile skin. Avoid plastic bed padding, which can do more harm than good by



trapping wetness against the skin. If he's incontinent, keep his skin clean and dry and use a moisture barrier cream.

- **Evaluate the patient's nutritional status.** An elderly patient is more likely to be undernourished or at risk for malnutrition. Carefully examine his eating habits and dental

status: If he's not getting enough protein, he can't produce collagen, and healing will be delayed.

Remember, preventing a pressure ulcer is basic patient care.

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*Lippincott Williams & Wilkins, Inc.*



## Delicious Summer Meal Ideas: For Older Adults

**T**his month we thought we would bring you some of our favorite summer meal ideas and recipes, as voted for by our clients.

Quick, easy and above all delicious – these ideas will help to make mealtimes enjoyable, throughout the summer and beyond.

As we age our interest in food can start to wane. Appetites decrease and illness and medication can also play a part in us

being less interested in food. When we add the heat of the summer into the mix, it can be difficult to maintain adequate nutrition, which is so important for all aspects of health.

Having tasty foods and simple light meals that are suitable for warmer weather can make all the difference. That's why we collected some of our client's favorites, to help provide a little inspiration for yourself or your loved one.

### Salmon

High in antioxidants, vitamins & minerals (including B12), protein and omega-3 fatty acids. These fatty acids are thought to help with brain function, joints and general well being.

### Egg Salad

Another great source of protein, eggs are an inexpensive sandwich filler. They contain a whole host of vitamins and minerals including zinc, iron, vitamins A, B2, B6, B12, K, D. Eggs also contain Vitamin E which helps to keep the skin and eyes healthy and strengthens the immune system.

### Tuna

Tuna has a very similar nutritional profile to salmon – also being high in omega-3 fatty acids. It can be mixed with mayonnaise and sweetcorn, for anyone that fancies a bit of a change.

### Ham & Cheese

Ham is also packed with protein and contains a range of B vitamins which help your body break food down into energy. Processed ham can contain a lot of sodium (salt) however, which can raise blood pressure. Cheese is a great source of calcium, protein, B vitamins and Vitamin A, which keeps your skin healthy, helps with vision in low light, and can also keep your immune system functioning properly.

Whilst ham and cheese both have a good nutrient profile they are both high in salt, and cheese also has a high level of saturated fat – which is why they are best enjoyed in moderation.

### Fresh salads

A firm favorite with our clients and our staff were fresh salads. Our client George told us how having ham salad for “high tea” every Sunday at his grandparents’ house, was the highlight of the week



when he was a boy.

Salads can be as basic or exotic as you like. Whether you firmly believe salad should only include lettuce, cucumber and tomatoes, or if you enjoy adding olives, seeds and dressings, there really is a salad for everyone. You can also add some protein such as ham, grilled chicken, tuna, eggs, chickpeas, mixed beans, or cottage cheese and add extras such as potato salad or hummus.

### Soup

Soup is often seen as a warming winter dish, but it can also be a nice light meal alternative in the summer. The wonderful thing about soup is that it can be batch cooked and frozen in portions, then defrosted when needed.

Another tasty meal that can be enjoyed hot or cold is chicken pasta salad.

To make this dish healthier use whole-wheat pasta, which is a complex carbohydrate – full of fibre it slowly releases energy over time, avoiding the spike in blood sugar that can come from white pasta (refined carbohydrate). Just ensure that once the pasta salad has been



cooked that it is refrigerated as soon as it cools down, to avoid the risk of food poisoning from the chicken.

### **Spanish Omelette**

Luis told us that one of his favorite dishes is “Tortilla de Patatas” which reminds him of family holidays in Spain. For anyone that doesn’t speak Spanish, this roughly translates to Potato Omelette.

Spanish Omelettes can be made with only 5 simple ingredients and can be eaten hot or cold. Cut them into slices and pair with cooked vegetables or a salad for a nutritious, mouth-watering meal.

Are you ready for dessert?

### **Strawberry cheesecake**

Fruity cheesecakes are a delicious dessert option during the summer months, and when paired with fruits and berries, they can be nutritious too. Strawberries are low-calorie berries, which do not rapidly boost blood sugar levels – making them a good fruit choice for Diabetics. They are full of antioxidants, vitamins C, K, folic acid and potassium.

Homemade scones can be frozen and then defrosted at room temperature, with a quick 10-second blast in the microwave or a couple of minutes warming in the oven, if only one or two scones are needed.

### **Fresh Fruits & Fruit Salads**

Nothing says summer quite like a fruit salad and our clients also thought so too.

Fruits are jam-packed with antioxidants, vitamins and minerals which are all extremely good for your health. Most fresh fruits also have a high water content, which can help you or your loved one to stay hydrated in the warmer weather.

Always be guided by your medical team as to which fruits are suitable for you. Some fruits are more suitable for diabetics than others, and some fruits such as Grapefruit cannot be eaten when taking certain medications.

### **Banana Split**

If, like Bob, you or your loved one enjoys a good old fashioned banana split, we have found the ultimate banana split recipe!

For something slightly less extravagant, a split banana with a scoop of your favorite ice cream, and some chocolate sauce will be equally tasty.

We hope that these summer meal ideas and recipes have given you some inspiration and got your taste buds tingling. It can be easy to get into a routine with food especially as we age; by trying new things, or going back to old favorites, food can become exciting and enjoyable once again – helping to encourage good nutrition to keep us healthy.

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