(A CART captioner is present and standing b (A CART captioner is present and standing by.) >> OPERATOR: Recording in progress. >> Good morning. And welcome to the National Coverage Determination analysis on treatment for Alzheimer's disease listening session. I'm Stephanie Costello, director of the partner relations group and the CMS office of communications and I will be moderating today's listening session. Today I'm joined by Tamara Jensen who is the director of the coverage and analysis group, and the center for clinical standards and quality. Before we begin, I have a few housekeeping tips. This call is being recorded and will be transcribed to serve as an official record as part of the National Coverage Determination or as you will hear it referenced here NCD. While members of the press are welcomed to attend the call, please note that all press and media questions should be committed using our media inquiries form which may be found at cms.gov/newsroom/media-inquiries. Today's listening session is an opportunity for CMS to hear public comments. As such, we are not gathering written comments or taking questions through the Zoom platform. We will also not be responding to the comments made or answering questions asked during the comment portion of the call. All written comments must be submitted to the NCD tracking document. A link to the tracking document is appearing on the screen, and will be up for the remainder of today's session. The list of today's speakers was compiled based off those who indicated through the registration process that they wanted to speak on today's listening session. We will do our best to get to as many speakers as possible. Each speaker will have approximately 3 to 5 minutes. We're keeping an eye on the time, and we'll politely ask those speaking to finish remarks on time. And with that, I will turn it over to Tamara Jensen, the director of the coverage and analysis group. Tamara? >> TAMARA: Thank you, Stephanie. Good morning, everyone. And thank you all for joining our listening session today. Again, my name is Tamara Syrek Jensen in the center for clinical standards and quality. As many of you know, aducanumab or Aduhelm was recently approved by the FDA. We will determine whether there's a national policy for Aduhelm and it will feature any monoclonal antibodies for an indication in use for treating Alzheimer dais ease. Aduhelm is currently the only monoclonal anty body to target amyloids. By engaging in the NCD process, we will determine whether the evidence supports improvements in health outcomes of adding Aduhelm as a national coverage treatment option for beneficiaries. The public process for NCDs remains a CMS cornerstone. CMS follows a longstanding process developed by Congress to determine whether a medical item or service can be covered nationally by Medicare. This includes whether an item or service is reasonable and necessary for the diagnosis of, and/or treatment of an illness or injury. NCDs are made through an evidence-based process that includes multiple opportunities for public participation. CMS developed NCDs using all relevant published evidence and feedback received from all stakeholders. The NCD process is open and it is critical that stakeholders provide input. We are listening to all feedback received. Through the NCD tracking sheet, CMS will continue to provide ongoing communications and updates to keep the public informed. Our goal at the end of this process is to provide the American public with clear, trusted, evidence-based decisions that has been a -- that has been through a thorough evidentiary analysis for Medicare beneficiaries. NCD announces when the CMS announce an item is under consideration or posting a notice or commonly referred to as a tracking sheet on the CMS coverage website and you can see the link displayed currently. CMS posts a specific tracking sheet for each item or service under review. The tracking sheet may include questions or issues the agency wants stakeholders such as medical societies, clinicians, researchers, patients, family and caregiver advocates as well as the general public to specifically comment on during the 30-day public comment period. For this specific NCD, the initial public comment period ends on August 11th, 2021. Weave view all comments and associated evidence to develop the proposed NCD and the decision memorandum. It contains an analysis of evidence that supported CMS's NCD conclusion. This phase of the process typically takes six months. CMS expected a proposed decision memorandum to be published no later than January 12th, 2022. Once the proposed NCD is available, the public has another opportunity to provide comment. This is the second 30-day public comment period. To ensure complete transparency, public comments received are posted on the CMS coverage group's website. Typically, a final NCD is available 90 days after the proposed NCD is published. The final NCD and decision memorandum are posted on the CMS coverage website with the NCD effective on the same day that we publish it. Therefore, a final NCD would be completed no later than April 12th, 2022. While the NCD process is underway, the Medicare contractors representing 12 jurisdictions across the country will continue to make the decisions regarding coverage for Aduhelm on a case-by-case basis, using all available evidence. Please note that Medicare payment rate and coding are developed outside of this NCD process. As Stephanie mentioned today -- as Stephanie mentioned today's listening session is an opportunity for CMS to hear public comment and we will not be responding to the comments made or answering questions asked during the comment portion of this call. Again, we appreciate your feedback and we look forward to hearing from all of you. Thank you. Stephanie? >> STEPHANIE: Thank you, Tamara. And now we will begin the listening session portion of the call. I will call on individuals and you will be unmuted to make your comments. Again, comments should be held 3 to 5 minutes and with that, I will call on those who have signed up to speak and the moderator will be unmuting your phone. First up, we have Maria Cario from the Alzheimer's Association. >> MARIA: Thank you very much. Can you hear me? >> MODERATOR: Yes, we can hear you, Maria. >> MARIA: I'm chief science officer for the Alzheimer's Association and on behalf of all of those living with Alzheimer's and their caregivers, I want to thank you for the opportunity to address you today and the CMS analysis group. I want to thank you particularly for being such a valued partner on the imaging dementia for amyloid scanning and idea study and the new idea study which is addressing underrepresented populations in terms of studying amyloid scan and impact on diagnosis and further, of course, outcomes. We're very grateful for our partnership with the CED programs and I would like to announce that our disclosures at the Alzheimer's Association are the following. We received 0.89% of our total contributed revenue from the biotechnology pharmaceutical diagnostic and clinical research industry, including 0.5% from Biogen and Eisai 0.15%. This can be found at Alz.org,/transparency. We strongly urge you to issue a favorable National Coverage Determination and make this and future Alzheimer's therapies available to all individuals who have the potential to benefit. As the leading voluntary health organization in Alzheimer's care support and research, each year we speak with hundreds of thousands of families through our 24/7, 365 days a year help line and serve hundreds of thousands more providing access and direct support across the country. Through our work, we see firsthand the devastating toll of Alzheimer's and what it takes on individuals, their carers and their families. I have lost two family members to Alzheimer's and related dementia in the last four years and know this myself personally. As all of you know aducanumab is the first of this class. It is first treatment to be approved for Alzheimer since 2003 and address underlying biology. The treatment should initiated in patients in patients with Alzheimer disease in stages at which they were studying the trials aducanumab was studied in these populations and showed that evidence of the buildup of plaques in the brain could, in fact, provide a reasonably likely important benefit to those patients. The population indicated in the FDA label is what we agree should be the one that can potentially benefit from treatment and who should be approved for reimbursement through CAG and CMS. This potential for benefit, though modest and not a cure, we understand can be considerably important, considering the early signs of Alzheimer's disease. Being able to stay in the impairment due to AD or early dementia stage for months or longer is something someone who has experienced this devastating disease would want for their loved one, more time to enjoy what time is actually meaningful. That time is priceless! And it's so important when there is no way out. Every single person with -- would receives a diagnosis of Alzheimer's disease will die with it or of it. As you consider coverage, we must of course consider the racial and ethnic populations that are impacted by Alzheimer's. Historically through what we understand are the social determinants of health. Older blacks are twice as likely to have Alzheimer's or other dementia, and older Hispanics are one and a half times likely. CMS and CAG to the 2021 on race, ethnicity and Alzheimer's in America. Discrimination remains a huge barrier and we are committed to eliminating all barriers as an organization and we are committed to supporting CMS towards its own efforts to that end. So this is the first of the new treatments to come. History has shown approvals invigorate the field. We know there's' pipeline. New treatments will become available in the coming few years. We know they are in the pipeline and the association is committed to supporting CMS in making coverage decisions and removing barriers to those treatments for all individuals who have the potential to benefit, including those populations disproportionately affected by this disease and who have been historically underrepresented and left out of healthcare. The association is grateful to CAG for all of your careful consideration and the evidence that you will be gathering and thank you for the opportunity to comment. >> MODERATOR: Thank you very much. Our next speaker is Sue Pression from the alliance for aging research. >> SUE: (Silence). >> MODERATOR: Sue, I believe you need to unmute yourself as well. Moderator, can you please unmute Sue Presson. >> Yes, I have. She needs to unmute on her end. >> STEFANIE: We'll come back to Sue. Our next speaker is AJ Price with Credit Suzi. >> MODERATOR: I don't see him. >> STEFANIE: Okay. Thank you. Our next speaker is Ian Kremer from Lead Coalition. The leaders engaged on Alzheimer's disease. >> MODERATOR: He's not coming up. >> STEFANIE: So Ian Kremer is not on as well? All right. Let's circle back and see if Sue Presson is ready to speak. >> SUE: I am so sorry. My mom, actually, called me. So I apologize. I stepped away. >> Hi, everybody. So my name is Sue Peshon and I serve as the CEO for the Alliance for Aging Research and I appreciate that CMS is doing these stakeholder calls. I have one request for the coverage and analysis group, just for the next stakeholder call on July 27th. I realize you guys are incredibly busy, but I just ask that you please adhere to the 24-hour notice for folks who are participating in the next call to let people know that they are up for public comment. I didn't get notified until 10:00 last night. So that's just one thing to keep in mind for the next call. The second request is the treatment under discussion during the NCD process. My understanding is that patients are currently being denied coverage at the local MA C. level and I ask that CMS please work swiftly with the sponsor company to determine coverage for the next nine to 12 months as you have done with other medical products under NCD discussion. Right now, I think every -- all the payers are left hanging and making decisions left and right not to cover. And then a couple of quick thicks around the process for this. I'm sure you saw, former CMS administrator, Mark McClemen, it would be ethical question for CMS to require its own separate randomized coverage with evidence development study on a drug where the indication has been approved by the FDA under accelerated approval. There's also other randomized trials underway by other sponsors for the same types of treatments and those will be reading out in the coming months. So I don't CMS needs to duplicate on that. I know it's been suggested to do an observational registry-type approach as you have done with other coverage with evidence development decisions. But we have had experience as CMS knows with other coverage with evidence development processes for devices used to treat heart valve disease and as a result of that experience, we have a couple of points to raise and just hope that is, you know, this can learn from those experiences. We would like the registry under the CED, if it is a CED, or under the NCD to basically say that it has to be strictly focused on answering the evidence questions that are raised by CMS. And know other types of questions from other academics or others who want to do studies to prove by certain providers should be doing this, or volume requirements or anything. It should be subject to timelines for CMS, and those should be specified in the coverage decision. We would like the registry stewards to public an annual report on the data that's collected, in a peer-reviewed publication that offers open access to that patients and families can see up-to-date results of the studdie to help with their treatment decision-making. And then we would like any type of charges by the registry stewards to be transparent, and not be more than, you know, a slightly above the cost to run the registries because it does otherwise restrict to larger academic centers and it prevents smaller hospitals to participate and to your points on wants to help with equity issues we think this would go a long way. We also think that it's very important that the process for what people are asking for in terms of the define of the coverage decision who gets to give the treatment and where the treatment is given is provided along the way so it's not just released in a draft comment format, but the questions are raised along the way so people can actually comment on those. Because when this is done in just sort of a here's a consensus statement, and CMS is just going with the consensus statement process, it leaves little room for any type of revision. And we would like to see this be a bit more -- (Audio drop) and last, I think that the point around making sure there's a beginning, middle and end to this process. Once it's decided, not -- not for the NCD process but for the study period itself, the observational study period that that be made as clear as possible. Because we have then it with PET, how it has dragged out. We're told we are waiting for publication. Publication has occurred. It's continued to be drawn out. So please be as transparent as possible about the timelines. The patients and the families deserve it. These CEDs with Taver and Tier, they can sometimes perpetuate inequity because when it's at the large academic centers, it's not as easy as communities of color to receive access. And it's 3 to 2% for Blacks and Hispanics. If it's relegated to that and specialty societies come in and they do their kind of territorial thing. I ask you to try to get this done as quickly as possible. Thank you so much for the time. >> STEFANIE: Thank you. Our next speaker is Robert Kenya from Prime Therapeutics. >> ROBERT: (Silence). >> MODERATOR: Robert, you need to click the unmute. >> STEFANIE: Robert Kenya. >> ROBERT: You have the wrong Robert. >> STEFANIE: Robert Kinwua. >> MODERATOR: He's not come up. >> STEFANIE: The next speaker is Max Linder. >> MODERATOR: No Max Linder. >> STEFANIE: Up next, we have Patricia Vensavega. >> MODERATOR: Yeah, I got her. >> STEFANIE: Great. Patricia, you can go ahead and unmute. >> PATRICIA: I'm a graduate student in Georgetown University's health and the public interest master's program. I'm currently an intern for and representing farmed out that educates healthcare professionals and students about pharmaceutical and medical device marketing practices. We ask CMS to refuse all coverage of Aduhelm and any other drugs approved only on the basis of reducing amyloid plaque. Question one, regarding important health outcomes. Treatment for Alzheimer's patients should improve cognitive function. Ideally the result would be restoration of loss function, however, the sensation of the patient is important. Also, treatment benefits should be durable, and benefits should for outweigh the harms. Aduhelm fails in all of these regards. It does not restore or improve cog any five function. It does not stop decline and it has a clinical inconsequential effect on delaying decline. Also it has an unacceptably high rate of adverse events. Up to 40% in the high dose group experiences brain swelling or brain bleeding, term -- Biogen recommends nonuse after 10 bleeding events. Patients experience headaches nausea, disorientation and altered mental status. These symptoms will not improve patients' lives. The fact that some adverse events including disorderrentation and confusion can't be easily differentiated from disease progression is highly problematic. Aduhelm is not benign. Patients who may have remained stable may experience. No drug should be paid for on reduce amyloid plaque. Now on to question three. Equity and inclusion. It's critical to have equity and inclusion in clinical trials and drug companies should not be able to sell to Black or minorities. Combining in the emerged and engaged trials, Biogen included 19 Black participants. That's less than 1%. Also only 104 or 3.2% were Latinx. Equity shouldn't be about equal access to ineffective and harmful drugs especially when that drug was not tested in the population it's aimed at. Unproven benefits and proven harms is a bad combination. We urge CMS not no cover Aduhelm in any population. Patients and their families need effective therapeutics not false hope. Refusing to cover this drug in any population is the best course to protect patients from the harmful effects of this drug. Thank you. >> STEFANIE: Thank you very much. Our next speaker is elion Caspy from the University of Connecticut. >> MODERATOR: Not coming up. >> STEFANIE: Okay. Moving on. Our next speaker is Adrian Ferberman. >> Good morning. My name is Adrian Fuberman, I'm a professor in pharmacology and physiology and the department of family medicine at Georgetown University medical center where I direct pharmed out that promotes rational subscribing. Aducanumab should not be covered by CMS because it doesn't work. It hurts people, and it has the potential to drain the resources of payers. Many drugs have been shown to reduce amyloid plaque, none of these, including aducanumab have shown a clinically significant benefit. None of the 25 trials of drugs that reduce plaque in Alzheimer's patients has been successful in treating the disease. The connection between Alzheimer's and amyloid is unclear. One study that followed normal elderly people for up to 16 years found that those with plaque and pathological brain changes typical of Alzheimer's had the same risk of cognitive decline. The goal is not to help plaque. The goal is to help patients. Not only are amyloid targeted drugs far from benign. They sometimes worsen the condition they are meant to treat. 40% of aducanumab patients will experience brain swelling or brain bleeds which are called arieE or ariaH. It sounds both benign and musical. It stands for amyloid-related imaging amnormallity but really this is drug-induced bleeding or swelling. Burdensome and expensive monitoring includes regular MRIs. Biogen recommends considering halting treatment only after ten bleeding events. CMS should refuse to cover aducanumab in any population. Biogen and Eisai are already spreading information. Their it's time we know website states wrongly that in 1 in 12 Americans 50 years of age or older have noticeable symptoms of MCI and states wrongly that MCI is most commonly due to Alzheimer's disease. Initiatives by Biogen and Eisai are scaring perfectly normal 50-year-olds that they have MCI because of Alzheimer's. The potential target is immense. Elders who occasionally mislay keys will be beating down the door for it. The FDA erred in approving this drug but CMS has the chance to do the right thing for public health which is to deny coverage for this ineffective and harmful drug. There are already proven and underused measures for dellaying cognitive decline, including deprescribing unneeded drugs, treating hypertension, addressing sleep apnea and increasing social interactions and exercise. One RCF found elders with mild cognitive impairment, who were assigned to learn ballroom dancing significantly improved. The Lancet had 12 modifiable risk factors that account for 40% of dementia, diabetes, depression and smoking. The most effective intervention and the one most relevant to CMS is hearing aids. Decreased hearing loss hastens cognitive decline and hearing aids reduce this decline. Hearing aids are an effective life enhancing, harmless intervention that Medicare doesn't cover. A pair of hearing aids would be less than a tenth of what the first year of Aduhelm costs. You should be covering hearing aids. There's no setting in which this treatment should be given to people. You should cover hearing aids and not aducanumab. Thank you. >> STEFANIE: Thank you very much. Our next speaker is Ian Kremer. Ian, you need to unmute. >> IAN: Good morning, can you hear me now? >> STEFANIE: Yes, I can. Thank you will. >> IAN: Sorry for my difficulty coming off mute and thank you for the NCD analysis and the opportunity to speak. My name is Ian Kramer. I'm the leaders engaged on Alzheimer disease. I want to begin by making clear, the comments I offer today represent my views exclusively. They do not necessarily represent the crews of the entire lead coalition or any of our individual member organizations or allies. I have been working on Alzheimer's and dementia professionally for almost 25 years and my family intermittently has experienced Alzheimer's disease and other forms of dementia for over 30 years. I have known thousands and thousands of families and individuals living with these conditions over that time. For me, this is both a professional and a deeply personal set of questions that CMS is posing. And I will start with question number one. In terms of the most important health outcome -- and there are many important health outcomes, I think they all come back to time. Any opportunity to significantly, whether it's months or ideally years to delay or slow decline is central to families like mine and millions of families like ours. Everything else ties to time. The ability to be an engaged decision-maker for all that will come after this earliest stage of disease. The opportunity to enjoy life at its fullest with as clear cognition as possible for as long as possible. As others have said, we understand that this particular drug, that has been FDA approved and those that will likely follow in the short term, are not cures. But I think it's important to remember while this is not a debate this morning, I do want to refer back to some of the comments made by a couple of other speakers. This is about the whole class. It's not about one drug. So criticisms and concerns that people may have about one product should not and must not limit access to future drugs that FD A will review and hopefully approve. This is not about those in phase III now. This is not a time limited NCD. For the moment, this is open ended. While that may change, we can't assume that this NCD will be reevaluated in a year or three years or five years. We just don't know that. To cut off access to all future drugs in this class, by declining coverage outright, would be a terrible mistake as a matter of policy. It would be an even worse, and I think unforgivable mistake in terms of humanity. We owe it to people that will take Aduhelm and for those that will take the drugs that will follow to study those drugs with real world evidence in as rigorous a way as possible, but they need that access. They deserve that access. And I will just say to the issue that was raised by one of the -- one the earlier speakers about alternatives. We don't have to treat them as either or. We should be doing absolutely everything we can to advance the public health interventions at the same time that we make available all the FDA approved medications. Families and individuals and clinicians deserve an opportunity to make their own choices based on the available evidence while we develop more evidence. Families like mine need hearing aids. We need interventions around social engagement. We need interventions like FDA-approved drug therapies. To the second question, amyloid confirmation is a must. That is at least going to be the case as long as there are questions about the degree of efficacy of amyloid clearance. We now have evidence that amyloid clearance makes a difference. I don't think any of us would say it's inclusive or entirely clear, but we have evidence. That's true in the Aduhelm trial and it's true in the phase III trials and phase II trials for going on with other companies. So let's get all of that evidence before we make a final decision on that. Let's continue to get amyloid confirmation so we make sure the right patients are the ones giving us real world evidence and are most likely to benefit from these therapies. As a side issue, I will say quickly, I know it's not covered by this NCD analysis, but it's incredibly important should CMS approve coverage for this class of medication, that CMS also revisit its earlier CED around head imaging. We need to make sure that there is full coverage for PET and the blood biomarkers and anything else that will help us get the amyloid confirmation that families like mine and millions of others need and deserve to make the right choices about the right medication at the right time. And then I will just make two quick points about health equity. As you are thinking about health equity, imagine you are but I will encourage you to be sure to consider both race and ethnicity, but also a range of other forms of health equity, including gender, socioeconomic status, intellectual and developmental disabilities, including Down's Syndrome, rural and other geographically isolated individuals, and issues like neurology deserts, making sure that this drug is available and drugs in its class are available equitably across the country, to all people who qualify in terms of amyloid confirmation and being at the right stage of disease, is incredibly important and that goes to my last point which is I think this must be a national rather than a regional coverage outcome. We cannot as a matter of policy, as a matter of medical equity, as a matter of social justice, we cannot have parts of country where individuals are excluded based on where they live. This has to be for everyone in America, regardless of race, ethnicity, socioeconomic status, intellectual capacity, and on down the list. So I ask you, and beg you to approve this class of drugs for all who fit the definition of amyloid confirmation and mild cognitive impairment and early or mild dementia. Thank you. >> STEFANIE: Thank you, Ian. Our next speaker is Susan Bunning from Medical Imaging and Technology Alliance. >> SUSAN: Good morning, everyone, my name is Susan Bunning, the industry director for Positron imaging, for MITA. I thank you for organizing this meeting. With the approval of Aduhelm, I would like to echo Ian Kremer's comment. The clinical appropriate patients or those who have the amyloid plaque the drug is targeting get identified to go on to treatment. Clinical assessments alone are limited in their ability to accurately diagnose patients, but FDA-approved amyloid and TA L. imaging PET agents are available today to detect the hallmark of MITA believes to enhance positive health outcomes from treatment, it's very more than to ensure the right patients are placed on the drugs. On the idea study steering committee, we learned three very important things. In over 11,400 patients, the amyloid PET diagnostic scan changed a patient's disease management over 60% of the time. And in 36% of the cases there was a change in diagnosis, as a result of the PET -- the patient as PET scan results. 77% of patients in this study had a diagnosis of Alzheimer's disease before the PET scan, but in over 3,100 of those scanned, the PET scan was negative, meaning no amyloid pathology could be detected in the brain. But amyloid PET diagnostics are currently not covered by CMS and while much is being debated by CMS and others on how to proceed for the treatment, we urge CMS immediately to open the noncoverage reconsideration request for amyloid PET that was submitted last September prevent the delay first ever disease-modifying treatment. We urge CMS to change its policy with regard to Medicare payment. The current situation, makes the new targeted diagnosis pharmaceuticals barrier. With regard to equity and inclusion, the follow-up study to IDEASs, new ideas focuses on minority populations. Enrollment challenges are the direct result of impact of CMS packaging payment policy. As an update to the GAO report, only about a handful of hospitals invited to date have accepted the participation. There were over 125 hospitals that participated in the original study. We urge CMS to consider the access barriers by the current coverage for amyloid and TAL diagnostic imaging that will enhance positive health outcomes and equity inclusion. Thank you for allowing me to comment today. >> STEFANIE: Thank you very much. Our next speaker is John Foster, Biogen trial participant. >> MODERATOR: He's not coming up. >> STEFANIE: Moving on to Carla Paulens. >> MODERATOR: She's not either. >> STEFANIE: Moving on we have Taja Plat from Carrington College. >> MODERATOR: No, not coming up. >> STEFANIE: Taja is not coming up either? >> MODERATOR: No. >> STEFANIE: Moving on to David Stankey, independent consultant, concerned citizen. David, you are on if you can just unmute. >> DAVID: Sorry. I will submit a written testimony later. >> STEFANIE: Great. Thank you very much. >> DAVID: Thank you. >> STEFANIE: Moving on to Paul Rudolph. Paul you are on. You can on. >> PAUL: Can you hear me? >> STEFANIE: I can. >> PAUL: I'm Paul Rudolph. For purposes of this discussion, I'm speaking on behalf of my clients the American Academy of Neurology and American Geriatrics Society and the Society of nuclear Energy with respect to the joint letter that the three societies submitted earlier this week. The letter was not directly about Aduhelm. They will each be submitting comments on coverage later on. What the letter concerned was the need for CMS to immediately cover PET scans for beta amyloid. We very much appreciate that CMS has proposed to -- for its most non-oncologic through the rulemaking society this year. Unfortunately that proposal does not include beta amyloid PET because there's an NCD on beta amyloid PET which limit it's to certain clinical trials regarding PET. Paradoxically, if it's finalized, there will be TA L. imaging but would still be noncoverring, beta amyloid PET. As everybody knows, beta amyloid PET positron ittivity was required for the participation in the aducanumab trials. We think it's imperative that patients immediately have access to PET scans and we suggest and we agree with what Sue Bunning said but we think there's a better way to immediately let patients have access to beta amyloid PET and that's by using the rulemaking process to immediately retire the current CED coverage which can be done through the interim final rule with comment on the back end. CMS could be free later on to change that, in connection with the coverage of aducanumab, and other monoclonal antibody treatment products, but right now, the only thing that patients have access to for determining whether they have amyloid plaque are CFS tests and while it's true that Biogen is paying for those, and so they are free, it requires a lumbar puncture and there are many, many, elderly people who cannot tolerate a lumbar punker or it's not indicated or would be dangerous, even done under ultrasound guidance. So Medicare patients don't have access to the one FDA-cleared test that is known to diagnose amyloid plaque and was used in these clinical trials. It is also well-known that many patients don't have amyloid plaque and right now, without making that available, there may be lots ever patients without plaque who are going to get aducanumab, and there's no evidence that those patients will benefit. In fact, those patients could be harmed because ARIA brain hemorrhages and brain edema. So on Monday, we sent a letter to the administrator, Chiquita brooks Lasure. We copied the whole team a tag on that letter and we would deeply, deeply appreciate it if CMS would strongly consider immediately issuing an interim final rule that would require the CED coverage of the beta amyloid PET and all three societies stand ready to work with CMS to answer questions, to meet with CMS on this extremely important issue for Medicare beneficiaries. Thank you very much. >> STEFANIE: Great. Thank you very much, Paul. Our next speaker is Miner Gashani from the society of nuclear medicine and molecular imaging. (Silence). You are on. You just need to unmute. >> MUNIR: Now I have the unmute button. Can you hear me well? >> STEFANIE: Yes, we can. >> MUNIR: I'm Munir Ghesani, thank you for permitting to provide the comments on the national coverage analysis for monoclonal antibodies target amyloid for the treatment of Alzheimer's disease during the stakeholder call. According to the Medicare physician fee schedule proposed rule for 2022, and as mentioned by Paul Rudolf earlier, TAL PET may be covered by CMS, though amyloid PET will not. Both are very important indicators of Alzheimer's disease and coverage will be necessary for both as Mormon know clonal antibody treatments for Alzheimer's disease become approved in the future. Amyloid PET scans were used in Biogen's clinical trials and covered by Medicare through coverage with evidence development. To identify suitable patients and to assess their therapy response. Currently, it is the only FDA approved diagnose I can to identify amyloid plaque, the sub stance that aducanumab targets. CFS is currently not approvedden aas Paul mentioned the CFS requires a lumbar puncture and all three biomarkers may be necessary to guarantee patient access, coverage for amyloid PET is of utmost importance. Others were not used to assess patient outcomes in the aducanumab trials. Many elderly patients are not ideal candidates for lumbar puncture due to an atomic constraints. They provide regional identification of amyloid in the brain, where the other biomarkers do not. They simply tell you the presence or the absence whereas the amyloid actually visually provides you distribution to assess in advance. Additionally without PET as a gatekeeper, you are potentially giving the drug to patients that was never evaluated in, which could result in toxic side effects and no clear benefit as was mentioned numerous times. CMS must eliminate the national noncoverage decision for amyloid PET. There are actually a couple of studies that have looked at it in details and one randomized trial using 618 patients found immediate notification of beta amyloid PET with increased likelihood of changes disease management, referred to a specialist at a three month versus delayed notification. Another large trial using more than 16,000 patients before and after study found beta amyloid PET associated with change in management in over 60% of patients with mild cognitive impairment or dementia of uncertainty. And change in 36% of patients which is a remarkable number. And so with all of these studies demonstrating that there's a direct utility of beta amyloid PET, in order to identify the patients more suitable for treatment, it is imperative as I would mention that the CMS reviews the national noncoverage for amyloid PET. Thank you for the opportunity to speak. >> STEFANIE: Thank you very much. Our next speaker is Dennis Selkoe. >> DENNIS: Can you hear me? >> STEFANIE: I can. >> DENNIS: I'm Dennis Selkoe, I cared for hundreds the patients with Alzheimer's disease and have seen the suffering of the patients and their family with this inexorably progressive degenerative disease that is ultimately favor. Therefore, I favor coverage by CMS of this class of agents that are potentially disease modifying, as everyone on the call knows this is the first time we have had a potentially disease-modifying agent approved and I think the accelerated approval mechanism that the FDA chose was appropriate for an outcome across both trials about aducanumab of marked amyloid lowering, which is a key biomarker change in Alzheimer's disease. Indeed, having actually done research on the amyloid and TAL alterations for the better part of 40 years, I can tell you that amyloid snot only a biomarker, but can be an actual cause of the disease. So people with rare autosomal dominant, and APP, unequivocally have Alzheimer's disease caused by amyloid buildup. It's extremely unlikely that sporadic or conventional Alzheimer's disease in late life, which looks very similar to the cases of AP P. and presomal, some individuals can have high amyloid levels and not have Alzheimer's, that is just that, a misunderstanding. Lesions can form before symptoms occurring and in some people, the lesions don't actually cause disease. We all know the example of athro sclerosis, but there are many patients would die of other reasons and have sometimes severe aathrosclerosis. It's an early pathogenic features of Alzheimer's that followed from everything we know scientifical from the enhancement of TAL. On this basis, we can say that the four anty bodies currently in phase three and in one case, with aducanumab done with phase III, if they remove amyloid and all four have been shown to do that already and in published work, are modifying Alzheimer's disease and therefore, Aduhelm and the three antibodies and the others that follow it are modifying the disease. I also want to point out that there's the unfortunate use in the lay public of brain swelling, and hemorrhage. ARIA-E is a correct scientific determine that was designated long before we knew about Aduhelm and its path to approval and ARIA-E represents a highly focal being sometimes multifocal minor edema in one region of the brain or another. It does not represent general brain swelling. Similarly, the hemorrhage that we're speaking of are microhemorrhages. They are not the major cerebral hemorrhage that most of us would be concerned about. Had several people in the aducanumab trials including patients who experienced ARIA-E, one knows that because of 25% of patients who get ARIA-E have symptoms whereas 75% in the trials did not have symptoms. And some impairment of orientation, the very things we don't want to see but the reality is that many effective medications have side effects and there's extensive information, that the vast majority of patients who are on a drug like Aduhelm or the drugs do not actually get symptoms from ARIA-E or ARIA-A. Approval by CMS for coverage for PET scans for amyloid is very important, but I should also say that in the center like ours at Bringham's Women's hospital Medical school, we will recognize on lumbar puncture. So it's very important to say that the earlier trials that targeted amyloid usually did not actually lower the amyloid. They targeted it but they did not have unequivocal evidence. The four antibodies being considered as a class for CMS coverage, all lowered amyloid plaques dramatically in the brain and that was associated with a variable 20 to 40% slowing of cognitive decline in all four of those. Therefore, I applaud CMS's taking of public comments on this very important disease modifying approach, and I applaud the fact that they are not talking solely by Aduhelm, but other amyloid antibodies, some of which have even more clear and robust evidence for benefit to patients but have not yet been approved. Importantly, the notion that amyloid buildup not direct directly linked to the cognitive abnormalities of disease, any more than the fact that several peripheral amyloid diseases in other tissues clearly cause organ failure, and the FDA has approved three different drugs to lower amyloid in the heart with clear cut benefit. Thank you very much for giving me the time to speak. >> STEFANIE: Great. Thank you very much. Our next speaker is Steven Saloway from Butler Hospital. Steven, I see you are on, if you can unmute. I can see you are on mute, but we still can't hear you. Sometimes people double mute. >> STEPHEN: Can you hear me? >> STEFANIE: Now we can. >> STEPHEN: Thank you for the opportunity to comment today. I'm Stephen Salloway, professor of the neurology and psychology at Brown Medical School and director of aging at Butler Hospital. I dedicated my career to treating patients with Alzheimer's disease. I treated 65 patients in the aducanumab in the phase I and phase III and I was the site PI for others. I'm also an expert in the management of ARIA. Alzheimer's disease is a progressive terminal illness without meaningful treatments to slow the disease course. It's encouraging that three anti-amyloid monoclonal antibodies have shown substantial amyloid lowering with some evidence of clinical benefit and I support the FDA decision for accelerated approval so that patients who may benefit can access to the medication while more research is conducted. More than 200 accelerated approvals of cancer drugs have had a remarkable impact on cancer treatment and we want the same thing for patients with Alzheimer's disease. We began and it closely follows the -- there's elevated amyloid on CFS or PET who have no contraindications such as cerebral hemorrhage. We have more than 100 patients on a waiting list who meet these criteria but the main factor delaying treatment is uncertainty about coverage. We want to ensure all patients can have access, not just those with financial means. Underrepresented, blacks and Latinos have higher rates of Alzheimer and it's critical that they have access as well. I'm concerned that patients who may benefit will not have access to treatment during the nine months prior to the NCD and may not be eligible for treatment later. There's guide use of aducanumab in clinical practice which should be published very soon, hopefully in the next week or so. We will also be disusing these guidelines in a section at AAIC, the international Alzheimer's conference next Tuesday. Treatment with aducanumab will require close partnerships between primary care and specialty providers to help identify patients who may benefit: Treatment will require access amyloid testing with clinicians knowledgeable in interpretation of these results and training and safety monitoring for clinicians and radiologists. It's important that CMS also cover the safety monitoring with MRI, to more approximate what we're seeing in the incidents in the clinical trials. The medication can be provided in an existing infusion centers. The goal of treatment is to preserve independence and quality of life for patients with early Alzheimer's disease. We will need to monitor with the patient and family, measures of cognition, activities of daily living, caregiver burden, and need for additional healthcare services. Let me give you an example of a patient on long-term aducanumab from our clinic. A 78-year-old retired school principal developed MCI due to Alzheimer's disease. He remained remarkably stable on open treatment with high dose aducanumab for five years, living at home, driving and socializing regularly. He only began to decline after aducanumab was stopped, and relied more on his family for help. But he's now doing better back on treatment. Aducanumab is the first drug approved for Alzheimer's in 18 years, and the first to target a key component of the disease. This approval represents a turning point and it's critical that all patients would may benefit have equal access so that we can build on this momentum and advance the treatment of Alzheimer's disease. Thank you. >> STEFANIE: Great. Thank you very much. Our next speaker is Jerry Varokis from Site of Peace. And Stephen, if you can remember to mute, please. Great. Sorry. Stephen, I think one of you is still unmuted. There we go. All right. Jerry Varoki, are you on? >> MODERATOR: No Jerry. >> STEFANIE: Okay. Thank you. Moving on, we have Kay Scanlan. >> MODERATOR: No Kay. I'm sorry, is she on? >> MODERATOR: No. >> STEFANIE: Okay. We're going to take just a moment to go back through the list at some of the earlier folks just to make sure that they didn't join later. So if we can recheck to see if AJ Rice is on. >> MODERATOR: No. >> STEFANIE: Robert Kinua. >> MODERATOR: No. >> STEFANIE: Max Linder? >> MODERATOR: No. >> STEFANIE: Elion caspi. >> MODERATOR: No. >> STEFANIE: John Foster. >> MODERATOR: No. >> STEFANIE: Carla Paulens? >> MODERATOR: No. >> STEFANIE: Taja Platt? >> MODERATOR: No. >> STEFANIE: Great. Thank you. Well, thank you everyone, for joining today. We appreciate you taking the time to join our listening session, either as a speaker or just as a participant listening to the comments. We encourage you, if you haven't made comments or if you want to continue to view other public comments, please visit the web page on your