Centers for Medicare & Medicaid Services
National Stakeholder Call on Final National Coverage Decision for Treatment of Alzheimer's Disease with Monoclonal Antibodies Directed Against Amyloid webinar
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Stefanie: Alright, looks like everyone's in attendance we'll go ahead and get started. Welcome. I'm Stefanie Costello, Director of the Partner Relations Group in the CMS, Office of Communications, and I'll be moderating the call today. This stakeholder call is an opportunity to provide a date on the final national coverage decision for treatment of Alzheimer's with monoclonal antibodies directed against amyloid, and to answer questions. This session is being recorded and will be transcribed. And also, this call is not for the press. The press are welcome to listen to the call. You can send questions to us. After remarks, we will open the floor for question and answers. If you wish to ask a question, please type it in the Q&A box at the bottom of the screen. We will do our best to get to as many questions as time allows. Now I will turn it over to the director of the Center for clinical standards and quality.

Dr. Fleisher: Thank you for joining us today to talk about the final national coverage determination from monoclonal antibodies for the treatment of Alzheimer's disease. I want to start out by saying that we appreciate the engagement by all stakeholders. We have received more than 10,000 comments. We heard you and we followed the signs to make changes. The final decision was driven by science, buying being -- by being based on the evidence. CMS follows a long-standing process developed by Congress to determine whether an item is reasonable or necessary for the diagnosis or treatment of an illness or injury to the Medicare population. This evidence-based approach and -- has included a review of peer reviewed document. The final decision ensures coverage for aducanumab and others that have received approval for the FDA or NIH across a broad scope of care settings. The decision also supports innovation and a certainty of coverage by creating a long-term coverage pathway for new drugs in this class that have obtained FDA approval without requiring a new national coverage determination. We will discuss those in more detail momentarily. As we think through Medicare coverage, it is important to remember that we are talking about a drug from mild cognitive impairment. This drug is directed at patients who were recently healthy and who may not have outward signs of dementia. As a physician, I know that there may be potential for promise with this treatment, however, while the drug is known to reduce plaque in the brain, there not currently evidence that this leads to a medical benefit in terms of cognition. In addition to the uncertain clinical benefits, the known risks associated with the drug include potentially fatal brain bleeds. Taken together, there is not currently sufficient evidence to support full coverage of this drug for people with Medicare until the statutory reasonable and necessary standard is met. CMS will gather additional evidence on the effectiveness and safety

of this drug by supporting rigorous studies by the FDA and NIH to determine if there is a clinical benefit for Medicare beneficiaries for drugs in this class. Future drugs in the pipeline, that domestic clinical benefits, will be covered so that patients have access. Coverage for these drugs will not require a randomized controlled trial. We anticipate that coverage in this case will include a data collection, such as a registry. We look forward to seeing the evidence for the drugs in the pipeline. We will continue to monitor future developments and requests of jugs and we are committed to exploring ways we can improve care for people with Alzheimer's. At this time, I will turn it over to Tamra, the director of the coverage and analysis group at CMS, to discuss the final decision in more detail.

Tamara: Good Afternoon. Actually, good morning, everyone. It is before noon. In January, CMS proposed of the all approved monoclonal antibodies that targeted amyloid would be covered for Medicare patients, only when included in a CMS approved randomized control trial or NIH trial. We are not finalizing that proposal. Informed by public comment, and the signs, they national coverage determination has evolved to ensure access for Medicare patients and provide certainty around coverage for future innovative drugs in this class. In making the final decision, as we mentioned previously, CMS reviewed over 250 pieces of literature, over 10,000 public comments, and new evidence. In terms of what has decision, the final national coverage determination does not restrict the patients who can participate in Medicare covered trials, offers broader access to across care settings, and -- for future drugs in this class. The first pathway provides coverage for drugs that are receiving accelerated approval from the FDA. CMS will cover drugs at the receive accelerated approval in the trials. CMS will no longer require a CMS approved randomized clinical trial and does not need to review or approve the FDA or NIH trial. The second pathway provides coverage for drugs receiving full approval through the FDA's traditional pathway. For those drugs in this class, that FDA approved under the traditional process, CMS will cover these drugs with evidence development. We anticipate that this requirement may be met by registry data collection. CMS will improve studies under the second pathway and criteria for approval are spelled out in the decision. Regarding the only currently approved drug in this class, aducanumab's FDA label is for those with mild cognitive impairment, that means people still going through daily life, so may still be working with the -- but with some memory loss. It is approved because it reduces plaque in the brain but as not yet known to treat Alzheimer's or lead to better patient outcome, such as increased function or increase cognition. And we also know that there are some glad -- were some bad clinical outcomes, like brain bleeds and possible death. We take all of these factors into consideration when evaluating evidence, particularly for a drug given to a relatively healthy population. Effective treatments for all timers disease are needed, and because of the burden of the devastating disease on the Medicare population, we believe that it is critical to provide covered pathways that support innovation while also supporting studies to answer questions about whether drugs in this class can improve health outcomes for Medicare patients. In summary, CMS wants to support access to innovative therapies that provide reasonable treatment to Medicare patients. There's two pathways for coverage, one offering coverage for all NIH and FDA clinical trials for accelerated approval drugs, and one

offering coverage for a wide array of studies for traditionally approved drugs, such as data collection and a registry. This decision is tailored to drugs in this class and it will not affect coverage of other accelerated approval drugs. We know that this is an evolving area so we also want to note that we intend to be flexible as new evidence is developed and comes out. We can always reconsider the coverage determination. In the past, we have previously reconsidered coverage determinations requiring clinical studies and removed the clinical study requirement when appropriate. I will now turn it over or back to Stefanie, thank you.

Stefanie: Thank you for those remarks and additional information. I want to spend our remaining time answering some of your questions. If you wish to ask a question, type it in the Q&A box located at the bottom of your screen. We will do our best to get to as many questions as allowed. Our first question is, why is CMS specifying coverage for future drugs that have not yet received FDA approval?

Tamara: Thank you for the question. What we have heard from stakeholders is they would like certainty on what the Medicare statute -- when a drug or item or service may meet the Medicare statute, what it says is that we are responsible for determining whether a particular item or service, or a drug is reasonable for the treatment of an illness. That's my we had the second coverage pathway, so that when a drug it goes through the FDA accelerated approval, then the manufacturers, clinicians and patients will know when CMS will cover those drugs and provide broader access to those drugs.

Stefanie: Great, thank you. Our next question, how can individuals find out about current clinical trials that are open right now?

Tamara: So, in the first pathway, we cover all or any FDA or NIH clinical trials without CMS interference, so we do not need to approve or review any of those trials. Since the FDA and NIH control the trials, we recommend you reaching out to the FDA or NIH to determine which or what trials are going on at this time.

Dr. Fleisher: We also suggest you reach out to your physicians or clinicians, who care for you. We expect that those who care for patients with Alzheimer's disease, particularly specialty centers, will be aware of these -- the trials that are ongoing.

Stefanie: Thank you. Ok, the next question is, will state Medicaid programs also be allowed to limit Medicaid program coverage to for medical trials? Is Medicaid required to cover this trial for Medicaid only individuals?

Dr. Fleisher: So, -- John: so, the drug is a covered drug. The manufacturers of the rebate program states -- say that states have to cover the drug, but can subject it to management techniques, such as authorization and step therapy. However, there is no authority or Medicaid statute to limit coverage to just individuals enrolled in a clinical trial. You cannot just cover

it Medicaid to those enrolled in a trial. So the state would have to cover it. They could subject it to management and other types of management techniques, but you could not limit it to coverage in just a clinical trial. As we did say in the communications that were released, that's for the non-eligible individuals. There is no requirement for coverage for their duly eligible individuals in Medicaid.

Stefanie: Great. Thank you. Our next question. What does coverage for FDA approved the trials for drugs with accelerated approval actually mean? Will CMS pay for drug diagnostic testing and safety monitoring for the upcoming FDA trial of aducanumab?

Tamara: We have not seen what those trials entail. So, once we have a protocol in house, we can determine, you know, paying for the drug and then the services around that drug. So we look forward to seeing that protocol.

Stefanie: A follow-up is, does this mean a patient must be in an approved trial to have coverage for monoclonal antibodies?

Tamara: Under the first pathway, what we proposed in January is that CMS would only cover the drug in a randomized controlled trial. We heard from over 10,000 public comments and they said that that was too restrictive. So in the final decision, if the drug has been improved under the FDA accelerated approval pathway, we will only cover that in a FDA or NIH trial because we need more information to make a determination on whether that particular drug is reasonable and necessary for the treatment of an illness. At this time, for the current drug of Aduhelm, it is only covered in the context of an FDA or NIH trial.

Stefanie: The decision refers to prospective comparative studies, that this could range from a registry with a compared Tory to pragmatic study. Today you used the term registry more specifically, can you clarify whether a registry is required or is an option? Would registry alone outside of the context of a clinical trial meet the requirements?

Dr. Fleisher: We look forward to seeing the protocols. A lot of this will depend upon the evidence that is observed for the second pathway, the full approval pathway. We anticipate that there will be a data collection with potentially a historic -- a group of historical patients to compare it to, but at this time we are awaiting what will happen for any future fully approved drugs. Importantly, we wanted to give clarity that patients will have access quickly if there is a fully improved agent in this class.

Stefanie: Thank you. Our next question, there is a lot being mentioned about clinical benefit as a rationale for the coverage decision. However, how does that NCD address the issues of diversity and inclusion in trials, which was also touted as a reason for the NCD?

Tamara: Diversity is extremely important to CMS. It was important in the proposed national

coverage determination, and it is important in the final determination. So, under the first coverage pathway for accelerated approved drugs, where we cover the drug in the context of an FDA or NIH trial, they are both committed to ensuring that there is diversity in any trial that they support. In addition, if a drug is approved under the FDA traditional approval process, diversity is extremely important in any CMS approved trial and it is a criterion in any protocol or any study that is submitted to CMS for approval. Thank you.

Stefanie: Alright. Is CMS taking any additional feedback on how we can partner with the agency to continue improving Alzheimer's disease moving forward?

Dr. Fleisher: CMS is always available for comment. In fact, one of the six pillars of the Administrator is engaging with their stakeholders. And therefore, we are always willing and excited to hear from those who want to advance any disease for patients for an we provide coverage. -- for whom we provide coverage.

Stefanie: That is all the time we have for today. We appreciate all of the questions that you asked and we were able to answer today. And we appreciate you all being on the call. This is going to be recorded and we will post it, so you could come back later and listen to that. We appreciate you being with us today. And we hope you have a great rest of the day.

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