Tumor Treatment Field Therapy (TTFT) – Open Meeting

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Dr. Robert Hoover, Jurisdiction C Medical Director

Good morning and welcome members of the public here in Baltimore and on the phone. I am Dr. Robert Hoover, DME MAC Medical Director for CGS, the Jurisdiction C Administrator, and one of the four DME MAC Medical Directors responsible for the proposed Tumor Treatment Field Therapy (TTFT) Local Coverage Determination (LCD).

We are here today to solicit comments on the proposed TTFT LCD. We'll be recording the meeting today, audio only, unlike our CAC where we had the YouTube video. This is audio only and we'll have the recording of this meeting and the comments that are made posted on each of the DME MAC websites following the meeting.

By signing in today, you are giving your consent to the use of your recorded voice and your comments. Please be mindful of sharing any personal health information in your verbal comments.

We also ask that any comments made today also be submitted in writing to TTFTLCDComments@cgsadmin.com and we will have that address up on the screen a little bit later. Again, that is TTFTLCDComments@cgsadmin.com. The comment period will close at 5:00pm Eastern Time on Monday, the 24th of June. Details for submitting comments are also available on the DME MAC websites.

We have several commenters in person here in Baltimore and additional commenters that pre-registered to speak via teleconference. Only registered commenters will be allowed to comment today at the meeting, but you can submit your comments as I mentioned, to the address, a moment ago.

For those commenting, we have allotted 5 minutes per speaker for the 3-hour meeting. Because some of our commenters that will be on the phone requested specific times to speak, because of clinic obligations, we are going to really have to enforce the 5-minute limit. For those of you here in the room that are speaking, we have yellow and red signs for 'one minute remaining' and 'stop,' respectively.

We ask that those on the phone you mute your line, not put them on hold. We don't want to hear music. Mute your phones when you are not speaking. Speakers should be prepared to begin their comments immediately when called upon and you will hear the Moderator's voice when you have one minute remaining.

Now, I will introduce the other DME MAC Medical Directors.

Dr. Fred Mamuya is Jurisdiction A's Medical Director at Noridian Healthcare Solutions. Jurisdiction A is comprised of 11 Northeast states and the District of Columbia. He is a cardiologist and has been a DME Medical Director for 6 years.

Dr. Stacey Brennan is Jurisdiction B's Medical Director at CGS Administrators, LLC. Jurisdiction B encompasses 7 Midwestern states. She is a Family Physician and has been a DME Medical Director for 11 years.

Dr. Peter Gurk is Jurisdiction D's Medical Director at Noridian Healthcare Solutions. Jurisdiction D is comprised of 17 Western states and 3 U.S. territories. He is an Emergency Room physician and has been a DME Medical Director for 6 years.

As I mentioned, I am Dr. Robert Hoover, Jurisdiction C Medical Director. Jurisdiction C encompasses 15 states, Puerto Rico and the U.S. Virgin Islands. I am an Internist by training and have been a DME Medical Director for over 20 years.

I'll now turn the microphone over to Dr. Mamuya for an overview of the proposed LCD.

Dr. Fred Mamuya

Thank you, Bob. Good morning everyone and welcome. Thank you for coming and thank you for the people on the phone. I am going to start with my usual disclaimer which is if I misspeak, please do not attribute that to my fellow Medical Directors and do not blame the agency. It will be a misspeak just from me alone.

I am going to, before I start, repeat something that Bob said because it is important I think, which is that please submit your comments in written form. That is the only way we can respond to them. It would be wonderful if you could submit them with some evidence-based rationale. Whether they are positive or negative, if you think there are ways to improve, please also add that to your comments along with some evidence based rationale for your suggestions.

Today we are here to get comments on a proposed policy that will extend tumor treatment field therapy (TTFT) for the first time to our Medicare beneficiaries. I won't go over the entire policy but as an overview, there are really two parts, I think, that we need to at least point out.

The first is Initial Coverage. In the policy, we have, I think, about seven criteria. One needs a histological diagnosis of GBM. The second is one needs to receive initial treatment, which has 3 arms: debulking surgery, chemotherapy and radiation. One needs to have no progression. The TTFT needs to be started within 7 weeks of the last dose of chemotherapy or radiotherapy. The care should be administered in a National Cancer Institute, NCI-designated, either cancer center, cancer research facility or comprehensive cancer center. One needs to be able to have a performance Karnofsky of at least 70. And the last one is for Medicare beneficiaries who can wear this therapy for at least 18 hours a day. And, when those 7, roughly, are met, that is when initial coverage begins.

The second part has to do with really what happens after 3 months and we call that, "Continued Coverage."

And, there are two steps there. One is an in-person evaluation by the treating practitioner to really document that the beneficiary continues to benefit from the therapy. The second piece to that is an adherence metric where the treating practitioner can look at the usage of TTFT and note that it is within the limits we talked about in the first part, which is roughly 18 hours a day.

That is a broad overview. We had urged everyone who was commenting today to really read the entire policy, and I hope all of you this morning have. With these comments, we welcome everyone to begin. Thank you.

Glenn von Nostitz

Good morning, my name is Glenn von Nostitz. Thank you for providing me the opportunity to share my experience with Optune today. My wife will speak after me about the proposed LCD coverage criteria.

I was diagnosed with a primary brain tumor in my left temporal lobe on January 1, 2016. I had my first resection on January 29, 2016. The pathology report indicated the Grade IV tumor, with IDH and MGMT negative, correlating with a median survival of 11 months. I was initially treated with radiation therapy and a Phase I immunotherapy trial. The treatment left me with deficits that may be apparent as I speak. Please be patient.

In October 2016, I was diagnosed with prognosis after learning that Optune was the only effective FDA approved treatment for unmethylated patients with recurrent GBM. I began using it before my second resection. I have used Optune continuously since December 2016.

My treatment with Optune was covered by Empire Blue Cross until I turned 65 on July 3, 2018. I'll be honest, Optune is a nuisance. It is not easy hauling around a 2-1/2-pound battery pack and wearing a bizarre wrap that must be changed 3 times a week and stings when you sweat. I subject myself to all this because I know that Optune is a major reason that I am still alive.

As I recover my strength, I am working again and recently completed a report on hospitals in New York. I have been able to spend time with my daughter, wife, mother, and brother. My device and I travelled to Israel and climbed the pyramids in Mexico. I bike all over, including to the hospital for treatment…a 30-mile round trip from my home. Three years ago, I never dreamed I would still be alive and able to do the things that make life worth living. My condition is not unique. Scores of other GBM survivors' credit Optune on blogs like Inspire.com and Facebook's Novocure Optune Support Group page.

Optune keeps so many patients alive that I do not understand how CMS could promulgate rules that would make it impossible for most GBM patients to obtain it, especially when the National Comprehensive Cancer Network now recommends Optune as a standard treatment option for newly diagnosed patients. Furthermore, it would be reprehensible to condemn thriving patients to disability and death simply because they have turned age 65 and now depend on Medicare.

My wife and I have been happily married for more than 36 years. We very much want to spend our golden years together and fear that CMS may make this impossible. Please do the right thing and give me more time with the people we love by rejecting the proposed coverage criteria and approve Optune for patients with progressions.

Thank you for this opportunity to share my experiences with Optune.

Margaret Stix

Good morning. My name is Margaret Stix, I am Glenn's wife. As he mentioned, I will focus on the proposed LCD coverage criteria and discuss how that coverage criteria, had it been in place, would have affected his treatment.

Thank you for this opportunity to comment.

I am going to start with number 2. The LCD proposes 7 conditions that must be met for Optune to be considered 'reasonable and necessary' for newly diagnosed patients. Four of these coverage criteria would have disqualified Glenn from using Optune.

To begin with, number 2 would restrict Optune to patients treated with the standard of care: maximum debulking, radiation with concomitant Temodar®. As Glenn mentioned, he was in a clinical trial instead of the standard of care. That clinical trial did not include Temodar®, and there is a very good reason for that. His tumor is unmethylated. Those of you who are familiar with the extensive research know that Temodar® does not work for unmethylated tumors. And, that half of GBM patients, like Glenn, have unmethylated tumors.

One of the mystifying aspects of the proposed criteria is why you would force patients who have unmethylated tumors to go through the grueling regimen of chemotherapy when it isn't going to work for them. But, unless these patients endure months of costly, debilitating and worthless chemotherapy, they would end up being ineligible for Optune under this proposed criterion.

So, this is of great concern. And obviously Glenn, having gone through a clinical trial that did not include Temodar®, would not have qualified for Optune, ultimately. He would have been disqualified by criterion number 2.

He also would have been barred from receiving Optune under coverage criterion 4, requiring that Optune 'start within 7 weeks of chemo-radiation'. Glenn started Optune 7 months after completing radiotherapy, remember, and no chemo-radiation and no radiation. He started it when his clinical trial failed, as most do.

So, we have this dilemma. We want to encourage people to participate in clinical trials so that we ultimately get a cure for this dreadful disease but, if you participate in a clinical trial and that clinical trial doesn't work, you're out of luck! You cannot get Optune under this criterion because

you have exhausted your 7 weeks. You would have to choose between Optune and a clinical trial. I have to say, the odds are better of surviving with Optune. Only 5% of drugs ever make it to approval through the clinical trial process.

If you were in that position, what would you choose? I think people would choose not to participate in clinical trials at all. Major cancer centers already have a really difficult time recruiting patients for clinical trials, so this criterion would make it probably nearly impossible for GBM patients to participate. That would undermine GBM research and delay a cure for this deadly disease.

Number 5 restricts use of Optune by patients diagnosed with progression. This presents two issues. First, patients with pseudo-progression or edema could become ineligible with incorrect diagnoses. Second, patients with progression would be barred from using Optune who could probably benefit.

We know this because Glenn was diagnosed with progression several times. In October 2016, an MRI showed that his tumor had doubled in size. However, after the resection, the biopsied tissue showed that he actually didn't. He must have had pseudo-progression. But he would not have been able to use Optune under this and that would have been a tragedy.

He has used Optune continuously since then, since December 2017, and it's worked. He has had a stable or shrinking tumor since. I have a few more copies of this. This is an MRI from this week, and you can barely see the tumor, despite the fact that he had had progression.

I wanted to talk about number 7 which is '18 hours a day'. This is completely unrealistic. The realistic statistic is 18 hours on average over the course of a month. But, you have sores which ensure you can't wear it. You also get MRIs which mean you have to have it off for about 6 hours a day if you are having an MRI.

Moderator – Margaret, I am going to have to stop you as time is up. Thank you.

Randy Horte

My name is Randy Horte, my wife, Jennifer, passed away about 6 months ago, unfortunately. She survived for 4-1/2 years. About 3-1/2 of those years, she was on Optune. I know that she would not have had the time, that we would not have had that time together that we did without Optune.

I am just going to speak to the criteria again because so many of these would have taken her completely out. The 7 weeks…she began treatment with Optune 11 weeks after hers. She went on Optune 3 years without any further progression. Even after her first progression, she had another 9 months on Optune. It was only after we had to stop Optune after the head wounds had gotten… For the last year of using it, we had been doing wound care and everything to keep her on it because we knew how much that meant.

The moment she went off of it, within a couple of weeks, she had another recurrence. We were going into a clinical trial at that point so we did not get her back on. Anyway, it was one delay after another and she passed. Maybe if we could have put her back on maybe she would still be here. I don't know. She had a lot of great, quality time and I know it was because of Optune. Anyway, the 7 weeks, she did not start until 11 weeks and had great time.

The progression rule, even after, there were two times during the three years where she was completely stable and progression-free. Where it was believed she had progression and it turned out both times were pseudo-progression. Later scans showed that wasn't to be the case. In fact, doctors at different facilities disagreed and then ultimately the later scans showed that the theory that it was pseudo-progression was true.

The surgery and the chemo, the last speaker mentioned about the clinical trials, so many trials are for upfront and if you undertake any of those, you wouldn't be able to do Optune. The 7 weeks alone. Maybe you don't do the Temodar® because of a clinical trial. My wife's case, there was no surgery possible because of the location of her tumor. She was multi-focal as well. So, she was multi-focal, inoperable and again, she survived 4-1/2 years. She was in the top 5% of all survivors. When you consider she was un-resected multi-focal, we are probably talking about top 1%. Again, I know it was because of Optune.

The idea that surgery is required…For people who can't have surgery and some people cannot, my wife could not because of location, this may be all they've got and now you are telling them they can't have it. After her first progression, she continued to use Optune. We felt out of all the possible things, it was her best course to stay on Optune and we got another 9 months before the next progression. So, this recurrence idea is also unfounded.

Let me speak to some of the other ones. That this has to be done at NCI-designated facility. We live in Los Angeles, we were fortunate to have many of those and we sought care at many facilities, but there are people who don't. And I will tell you, as far as using the device; I was able to do that for her out of my house. Other than the initial consultation with the doctor, we never once saw a doctor regarding the use of Optune. It just wasn't necessary, it's not needed.

There are people who do not live close to an NCI-designated facility. I could not imagine if we happened to live somewhere and we were 4 hours away there is so much time... The initial, you are going every day for the first 30 days because of the radiation. So, that alone you're not going to pick somewhere, you can't pick somewhere that is long unless you have lots of resources and money to stay somewhere for a month and uproot your life. Then, afterwards, she had to go back every week for the first year she was on chemo because it affected her platelets pretty bad, so we were monitoring her blood pretty aggressively. Then, every four weeks for an MRI. Just to be able to do that and then if you have to drive so far to get to an NCI facility…and some states don't even have an NCI facility. Let alone the fatigue, when she had cancer, the idea of doing those kind of days would have taken too much out of her and too much out of the time she had.

This device, the beauty of it, is that it can be done anywhere. Once someone is trained, the caregiver, to use it, it can be done anywhere. It doesn't need to be done near a specific hospital.

Thank you so much and I really do hope you reconsider these restrictions.

Matt Anthony

My name is Matt Anthony. Professionally, I have worked in Marketing throughout my career, but I am speaking today as the founder and president of the Head for the Cure Foundation on behalf of brain tumor patients facing among the most serious of cancer diagnoses, glioblastoma multiforme, commonly known as GBM.

I started Head for the Cure in 2003 following the death of my then 37-year-old brother, Chris, from GBM. For context, HFC supports brain cancer patients and caregivers across the country in three distinct ways.

First, we build awareness of the seriousness of this disease and the challenges faced by people with malignant brain tumors. Second, we raise funds for clinical research and advocacy programs. Third and I believe most importantly, we inspire hope for their life ahead and the lives of others facing the same diagnosis.

We implement these strategies through a series of community-based events across the country, mostly 5K runs and walks. In 2019, we will produce and host 28 5Ks in cities across the country, each of which support the aforementioned pillars of awareness, funding, and hope. This year alone, more than 25,000 people will participate or volunteer at a Head for the Cure event in cities from Seattle to Midland Texas, from Wichita Kansas, to New York City.

At each event in every city big and small, we welcome hundreds of brain tumor patients and scores of GBM patients.

Each of those patients and their caregivers are living their lives to the fullest they can while engaged or pursing the best therapy to extend their lives and offer the very best quality of life. They have many worries. Medicare coverage for an FDA-approved therapy, specifically Optune, because they happen to live or receive treatment in a geographically inaccessible area, should not be among those worries.

The current requirement for Optune therapy is that a patient must receive care at an NCI-designated cancer facility. When possible, Head for the Cure encourages all brain tumor patients to be treated at major brain tumor centers, many of which are NCI centers. This, however, is not always practical…there are issues of travel and expense.

Some of the patients have neurological problems that preclude travel. Finances become an immediate issue particularly since many, if not most of these patients, must suspend work after diagnosis. It is simply unfair to prevent treatment for these patients because of where they live. What's more is the majority of Neuro-Oncologists treating GBM patients do so in their community-based hospital or health center. These centers are not NCI-designated facilities. There are some states that don't even have an NCI-designated cancer center. In this case, what are these patients expected to do?

Finally, if all GBM patients across our country were to seek treatment only at major cancer centers, those centers simply cannot handle the capacity to treat up to 15,000 GBM patients each year, newly diagnosed.

On behalf of the nearly 700,000 people living with a brain tumor today, and the nearly 15,000 newly diagnosed GBM patients each year, and all those who love them, I implore the LCD to remove this restriction for Optune therapy. Thank you.

Debbie Robins

My name is Debbie Robins and I am the Director of Corporate & Foundation Relations for the American Brain Tumor Association. Our organization is the oldest patient advocacy organization in the United States, dedicated to supporting medical research and delivering information and support for patients and caregivers impacted by a brain tumor.

On behalf of the American Brain Tumor Association and the patient community we serve, we applaud the committee for recommending reimbursement coverage of TTFT for Medicare beneficiaries who are newly diagnosed with GBM. We do, however, have significant concerns with the proposed LCD as the proposed requirements impose restrictions not reflected within the FDA's prescribing label, nor reflected within the scientific evidence validating the usage, efficacy and safety of this therapy.

A GBM diagnosis is incurable. Once diagnosed, the median survival is a mere 14-15 months following standard of care (surgery, radiation and chemotherapy).

Throughout the history of this unforgiving disease, few medical interventions have been discovered. In fact, during the last 10 years, TTFT has been the only new treatment option approved by the FDA to extend overall survival of a patient diagnosed with GBM.

The proposed LCD for TTFT creates an unjustifiable barrier to access for the patient by requiring access to NCI-designated cancer centers in extended duration of prescribed use. As Medicare chooses to restrict TTFT reimbursement by instating these requirements, Medicare beneficiaries will not only be at risk for inequitable access to life-extending treatment options but may be deterred from obtaining the treatment that they need and deserve.

Considering 80% of cancer patients are cared for within a community setting, imposing criteria requiring a prescription at an NCI-designated cancer center creates a significant barrier for this patient population to access this FDA approved life-extending care.

This proposed criterion is unjustified. Neither the scientific evidence nor the FDA label makes any indication that a particular sub-set of healthcare providers should be designated in order to preserve or deliver better patient care.

A patient newly diagnosed with GBM living in Boise Idaho, for example, would likely be diagnosed by a local healthcare provider. Based on the proposed criteria after invasive brain surgery followed by radiation, this patient would likely need to travel to another state, driving 6-7 or more hours to access an NCI-designated center.

Beyond concerns associated with continuity of care, it is important to understand that a patient with GBM is likely to have health implications affecting cognitive functions and overall health. You cannot require a patient with GBM to have the functional and financial ability to travel to an NCI-designated cancer center to receive life-extending care. This is a significant barrier to equitable access.

Furthermore, the proposed LCD requires a duration of use beyond what is designated within the FDA label. The proposed language would require patients with GBM to wear the device for 18 hours a day. This requirement is not reflected in the FDA's indication of use, and it does not empower the healthcare provider to modify duration based on patient health or side effects,

such as skin irritation. If a patient has skin irritation due to usage, the healthcare provider would likely adjust usage duration until the skin is healed.

If this course of action (designed to address a common but minimal side effect) is advised, then according to your proposed duration criteria, the patient would no longer be reimbursed. Please modify the proposed criteria to an average of 12 hours per day or remove duration of use from the criteria altogether.

The American Brain Tumor Association strongly urges the Review Committee to consider the impact of these implications and consider reflecting the guidelines set forth by the FDA and supported by scientific evidence. Please do not inflict barriers to care that would impede a patient with GBM to have access to life-extending treatment.

Thank you.

Lainey Titus Samant

Hi, thank you. My name is Lainey Titus Samant and I'm the Director of Advocacy for the National Brain Tumor Society. I appreciate your consideration of my comments today.

The Mission of the National Brain Tumor Society is to unrelentingly invest in, mobilize and unite our community to discover a cure, deliver effective treatments and advocate for patients and their care partners.

Today I am sharing these comments on behalf of those patients and care partners across the country who are living with a GBM and to advocate on behalf of access to an FDA approved effective treatment. Despite the fact that GBM was first described in medical and scientific literature in the 1920s, only four drugs and one medical device has been approved by the FDA to treat GBM and mortality rates have shown little change over the past 30 years.

All patients, including Medicare patients, must have access to all of the FDA approved therapies for GBM so that they can decide (along with their doctors), the best course of treatment to fight this aggressive disease. As one of those therapies, TTFT is an important option for both newly diagnosed and recurring GBM. Coverage of TTFT should be consistent with FDA approved labelling and should not include additional restrictions unsupported by either peer reviewed evidence or current medical practice.

The proposed LCD indicates the coverage will be denied if a patient does not meet certain requirements. One such requirement is that the patient is receiving care at NCI-designated cancer center, comprehensive cancer center or cancer research network facility.

While similar to our colleague organizations, we encourage patients to seek care at NCI-designated centers; it is not always feasible as patients may face logistical or financial barriers to accessing those centers. Additionally, requiring highly specialized doctors at these centers to provide bi-monthly basic monitoring would cause an unnecessary burden to their caseload when they could instead be conducting research or meeting with patients in need of treatment planning.

Over 1,000 providers across the country have received extensive training on the use of TTFT and can provide the monitoring support necessary for patients using the device. Further restrictions on location of those providers should be removed from the LCD.

In addition, the requirement that patients must use the TTFT for at least 18 hours a day also creates unnecessary barriers to treatment coverage. While the peer review literature suggests a greater benefit to longer usage, it also indicates that patients using TTFT an average of 12 hours per day saw statistically significant improvement in overall survival. This stringent requirement is not consistent with available data on the effectiveness of TTFT nor is it consistent with standard practice of commercial insurers. Please remove this provision entirely or make it more reasonable such as requiring an average amount of usage over the course of a month.

Finally, the requirement that a patient begin TTFT no more than 7 weeks post chemo therapy or radiation is also too stringent when dealing with GBM patients. Many scenarios may prevent the medically fragile patient from beginning treatment within that 7-week window including side effects from radiation. On a personal note, my Dad had extensive burns on his scalp from radiation treatment when he had his brain tumor. I can imagine if TTFT were available at the

time, he would not have been able to use it at that point. This restriction is not consistent with commercial insurance coverage policies and should be removed.

The brain tumor community was encouraged by the FDA approval of TTFT for newly diagnosed and recurring GBM patients. As mentioned, few other treatment options do exist. However, treatments are only beneficial if patients have the ability to access them. Medicare coverage of TTFT should be consistent with FDA labelling both for newly diagnosed and recurring GBM patients to give every patient who is able a chance to access the therapy.

Please expedite the final LCD with those suggested revisions so that Medicare patients can receive the same coverage that their counterparts with commercial insurance have been receiving for years. Thank you for your consideration.

Vince Rock

Good morning. My name is Vince Rock. I am a Master's prepared licensed clinical social worker and serve as a Manager of Patient Services for the American Brain Tumor Association (ABTA). My role with the ABTA is to provide information and services for the brain tumor community.

Within this role, my team and I answer calls to the ABTA Care Line from patients and caregivers who are impacted by a brain tumor diagnosis. Last year alone, we personally responded to over 1,500 calls and emails from this community. Based on the insights gleaned from speaking directly with patients and caregivers, I believe it is critical that the committee understand the anticipated consequences of the proposed LCD coverage criteria for TTFT.

The proposed coverage criteria requiring a patient to access treatment solely through an NCI-designated cancer center will undoubtedly impede a vulnerable population's access to life-extending care. First, it is important to acknowledge the overall health of a typical Medicare beneficiary: an older adult who has is newly diagnosed with GBM.

As my colleague shared earlier, approximately 60% of the GBM patient community are cared for within the community setting and half of all Medicare beneficiaries live on an annual per capita income of less than $26,200. Upon diagnosis, the patient can be in a state of shock and disbelief. Quickly advised to undergo brain surgery, the patient completes surgery typically within one week following diagnosis. Radiation to the brain follows and then chemotherapy. By this point, the patient has 3 members of his/her health care team and the patient can be emotionally and physically depleted…but it is not over.

Following standard of care treatment, patients treated for GBM often begin to notice cognitive side effects, extreme fatigue, coordination difficulties, seizures, physical limitations with walking and mobility, incontinence and other difficult symptoms and side effects. And now based on the proposed LCD coverage criteria, this patient will be required to travel to an NCI-designated cancer center in order to receive FDA approved treatment to extend his/her life.

If a patient with GBM does not live in or have physical and financial ability to travel to a metropolitan city with an NCI-designated cancer center, the patient will be denied access to a proven, life-extending treatment due to geographical and financial limitations along with the burden of symptoms and side effects.

And if the patient is lucky enough to have a caregiver to travel with him/her to the designated center, and assuming it will be required to return time and time again, the proposed LCD coverage criteria now creates implications for the caregiver as well. Asking the caregiver to take several days trips many miles away may be inhibited by work-related commitments or financial limitations, not to mention day-to-day caregiving.

Should the Committee move forward with the proposed criteria, will Medicare provide reimbursement for transportation services utilized to access a Medicare required treatment center?

If a caregiver is unable to take time off from work (to travel and support the patient who demonstrates cognitive decline), will Medicare provide reimbursement for a Nurse Case Manager or Care Coordinator to help the patient travel to the Medicare required treatment center?

Without doubt, the proposed coverage criteria will place additional, unnecessary burdens and obstacles in the way of patient care during an already burdensome situation, rather than

empowering patients and healthcare providers to make appropriate treatment decisions together.

Please refrain from establishing the proposed LCD coverage criteria for TTFT and let the decision of how to best treat this aggressive disease be between the healthcare provider and a patient. Thank you.

Nadia Spawn

Good Morning. My name is Nadia Spawn. I am a Master's prepared registered oncology nurse, a former insurance nurse case manager and a current Director of Patient Services for the American Brain Tumor Association. I have first-hand experience working with patients diagnosed with GBM and I understand the impact that insurance regulations can have on care outcomes.

On behalf of the ABTA and the GBM community, I urge you to reconsider the proposed LCD coverage criteria. The short and long-term implications of these criteria will impact these patients access to life-extending treatment, restrict the decision-making ability of healthcare professionals and disrupt the continuity of care along the patient's course of treatment.

The mission of Medicare is to ensure that the voices and needs of the populations we represent are present as the agency is developing, implementing and evaluating its programs and policies. The vision of Medicare is that all CMS beneficiaries have achieved their highest level of health, and that disparity in health care quality and access has been eliminated.

The proposed LCD for TTF creates an unjustifiable barrier to access for the patient by requiring access to NCI-designated cancer centers. If Medicare chooses to restrict TTF reimbursement by initiating these criteria,

Medicare beneficiaries who are newly diagnosed with GBM will not only be at risk for inequitable access to a life-extending treatment option but they may be deterred from obtaining the treatment that they need and deserve.

This is in direct conflict with Medicare's stated vision. The proposed LCD coverage criteria violate Medicare's rights and protection for everyone in Medicare. Within a patient's rights, Medicare commits to providing patients with access to doctors, specialists and hospitals. By limiting a patient's access to life-extending treatment, by not only allowing patients to access a healthcare specialist at an NCI-designated cancer center, you are creating a significant barrier to this patient's rights.

A patient who has already received standard of care treatment and has established a working relationship with a local healthcare team, should not be forced to seek treatment elsewhere. The treating provider will already have established the four elements of a provider-patient relationship, which are trust, knowledge, regard and loyalty. By disrupting the provider-patient relationship for insurance purposes, Medicare is negatively impacting the health outcomes of the patient.

Is Medicare implying through these proposed restrictions that medical institutions not designated by NCI lack quality providers to prescribe and administer evidence-based FDA approved treatments and care to patients? This restriction will instigate a chain of events by which a patient's care management could be passed off between providers only to fall through the cracks due to lack of continuity and accountability over the patient's care.

Who will manage side effects related to treatment and who will monitor the treatment outcomes? Ultimately, the decision about whether or not a patient is eligible for this therapy should be one between the patient and the healthcare provider of their choice. By imposing strict criteria that pose a barrier to access, Medicare is hindering options of both patients and healthcare providers during an already difficult time of limited treatment options.

Please do not deny patients diagnosed with GBM from an FDA approved life-extending treatment option by requiring provider care through an NCI-designated cancer center. An aging population is already a vulnerable population. Add a GBM diagnosis along with brain surgery and brain radiation, and you will likely see a highly impaired patient who will be deterred by the expense of travel required to an NCI-designated cancer center in order to access this FDA approved treatment to live longer.

Please stand by your mission and stand by your vision by basing coverage criteria for TTF therapy on the evidence-based data reviewed and approved by the FDA. Providing patients, who are newly diagnosed with GBM, with equitable access to treatment and care is an essential right under the Medicare mission. Thank you very much for your time.

Ralph DeVitto

My name is Ralph DeVitto. I am President and CEO of the American Brain Tumor Association.

For 46 years, the American Brain Tumor Association has worked to advance the understanding and treatment of brain tumors with the goal of improving, extending and ultimately saving the lives of those impacted by a brain tumor diagnosis.

Unfortunately, the treatment landscape for GBM has remained relatively unchanged until recently when medical innovation led to the discovery of TTFT, the first FDA approved medical device proven to extend overall survival.

Supporting the brain tumor community for nearly five decades comes with an intrinsic understanding of this unforgiving and life-stealing disease. It is from this perspective that the ABTA strongly contests the proposed LCD coverage limitations on TTFT based on locality and duration of use.

These proposed coverage limitations impose restrictions not reflected within the FDA prescribing label, nor reflected within the scientific evidence validating the usage, efficacy and safety of this therapy.

On behalf of the ABTA and the GBM patient community, I urge you to reconsider the proposed LCD coverage criteria. The short and long-term implications of these criteria will impact a patient's accessibility to life-extending treatment, restrict decision-making ability of healthcare professionals and the overall quality of care along the patient's treatment journey.

First and foremost, I want to address the impact of a patient's ability to access an NCI-designated cancer center. NCI cancer centers are not available in every state (as you have heard), and for the most part, they tend to be located in major cities. The majority of cancer patients are being cared for by healthcare professionals within a community setting. Many diagnosed with GBM will need the ability to travel long distances or have a caregiver who can travel with them to a designated facility. Not only do these proposed criteria impact a patient's ability to access life-extending treatment, there are no scientific grounds supporting the proposed criteria.

Secondly, beyond imposing criteria positions that an NCI designated professional is more treatable practitioner than other professionals. The duration of use criteria takes away the ability and responsibility of healthcare professionals to appropriately care for their patients.

TTFT data has shown modest side effects. One of those is skin irritation and rash. Based on data provided to the FDA, when healthcare professionals adjusted the duration of use, patients were able to continue usage of this therapy. Based on the proposed LCD criteria, a healthcare professional will not be able to modify duration of use without financial penalty to the patient as coverage would be denied if the device was not used for 18 hours a day. Please modify the proposed criteria to an average of 12 hours per day.

Finally, we are concerned with the continuity of care for the patient that could be unjustly interrupted and contribute to substandard care of the patient. There is real potential that many patients will be juggled between a local healthcare professional and the NCI professional requiring cohesive communications between both practitioners which unfortunately, can be a challenge when practitioners are not affiliated with the same medical institution.

In closing, I ask the Committee to take a moment to step into the shoes of a patient diagnosed with GBM.

Please don't place unnecessary burdens upon the patient population. Give all patients newly diagnosed with GBM a chance to live longer. Thank you.

Nicole Willmarth

Thank you for taking time to hear my comments today. My name is Nicole Willmarth. I am the Chief Mission Officer of the American Brain Tumor Association.

As you have heard from my colleagues, the ABTA has worked to advance the understanding and treatment of brain tumors with the goal of improving, extending and ultimately saving the lives of those impacted with a brain tumor diagnosis.

With a PhD in Cellular Molecular Biology and an author of 17 peer review publications, please know that my perspective is steeped in the value of evidence-based medicine.

As a researcher and representative of the brain tumor community, I believe the proposed TTFT LCD coverage criteria does not reflect the FDA approved label and will impose unintentional and unnecessary harm to an already vulnerable patient population who are newly diagnosed with GBM.

Current standard of care consisting of surgery, chemotherapy and radiation is not enough to preclude one from the devastation of this fatal disease. With the FDA's approval of TTFT, patients newly diagnosed with GBM and healthcare providers finally have a treatment option proven to extend overall survival with minimal side effects, allowing patients to live longer with a better quality of life.

The FDA approval of TTFT was based on extensive clinical data clearly demonstrating progression-free and overall survival. Moreover, the clinical data withstood the rigorous FDA pre-market review process for medical devices requiring additional efficacy and safety data compared to evaluation of therapeutic. Based on this evidence, TTFT is now reimbursed by nearly every private payer in the U.S., giving patients newly diagnosed with GBM the potential to live longer.

The proposed LCD states the coverage criteria are designed to address evidence gaps that preclude unreserved support for the use of TTFT. Medicare should not address perceived gaps with coverage criteria that are not evidence based.

Please refrain from establishing the proposed LCD coverage criteria for TTFT unless the decision of how best to treat this aggressive and most often fatal disease reside between the healthcare provider and the patient. Thank you.

Jenna Heilman

As Executive Director for Head for the Cure Foundation we strive to raise awareness, funds for research and programs and help for the population of brain tumor patients who are fighting every day.

With a disease that has taken so many lives, hope is something that can be hard to come by. Many GBM patients on Optune have now seen improvement not only to the length of their life but most important, the quality of their lives.

Patients who hear that dreaded diagnosis of GBM now have options and hope. Optune is the standard of care that should be available to all who qualify for the treatment. Without it, we would not get to see GBM patients like Rose in Cleveland, who in her late 60's, was able to celebrate with more than 600 people as she crossed the finish line of a 5K, something that would not have been possible without Optune.

Along with my colleagues, I ask that the restriction for treatment to only occur at NCI-designated clinics be removed. Brain tumors do not discriminate. They can happen to anyone at any place at any time. Treatment options should not penalize patients who live in areas without NCI-designated centers and simply don't have the means to travel to another city for treatment.

Another restriction I would like to speak about is the requirement that patients on Medicare utilize this treatment for a minimum of 18 hours a day. While the peer reviewed literature supports the premise that the more time using the treatment, the better results. The literature also supports that patients utilizing Optune at least an average of 12 hours a day resulted in improvement in overall survival compared to just Temozolomide.

Certain patients have skin irritations or treatment that may require them to remove the device for longer periods of time. They shouldn't be fearful that option would lead to losing their coverage of this life-saving tool.

We ask to change this to an average of 12 hours a day.

We also ask that this be expedited as soon as possible. Patients with Medicare coverage have not been able to receive readily available treatment for this incredibly fast-moving type of brain cancer with just a mean survival of 14-16 months. This process has taken nearly a year and patients simply do not have this kind of time.

Please consider removing these restrictions to allow access for all who desperately need Optune treatment.

Thank you for your time.

Al Musella

Good Morning. My name is Al Musella. I am the President and Founder of the Musella Foundation For Brain Tumor Research and Information, Inc. a 501(c) (3) nonprofit public charity dedicated to helping brain tumor patients. I have interacted with tens of thousands of brain tumor patients over the last 25 years and went through this battle with 2 relatives who died of Glioblastoma. As a disclosure, Novocure is a sponsor of the foundation I work for and they have provided food for me.

I applaud your decision to cover Optune for newly diagnosed Glioblastoma patients. However, I would question the decision to limit coverage with such severe restrictions. Glioblastoma is a horrendous diagnosis and these patients need fast, easy access to the best approved treatments.

I object to all of the restrictions:

1. "Must receive care at a NCI designated cancer facility." My organization encourages all brain tumor patients to be treated at major brain tumors centers. However, it is not always practical. Many of these patients have neurological problems, fatigue, nausea, an increased risk of phlebitis and some cannot fly or sit in a car for long periods of time. This is a treatment that is done at home by patients and their families. There is no need for these patients to go to the major centers for their treatment. This restriction makes no sense at all. The majority of patients are not treated at major centers and these centers do not have the capacity to treat all GBM patients. So please remove this restriction.

2. "Patients may not have progression as defined by the RANO criteria." The problem with this is twofold: First, about half of all patients will show progression based on RANO within the first month of completion of radiation. About half of those patients will have pseudoprogression, which means that they do not really have progression –it's only the appearance of progression on MRI due to treatment effects. So a quarter of patients will be denied treatment under this restriction without really having progression. There is currently no sure way to differentiate true progression from pseudoprogression. Second, even if they have progression at this point, Optune is still the best choice of treatment for most. It has less chance of working but there is nothing better available now. So please remove this restriction.

3. "Must have had maximal debulking surgery, followed by radiation with concomitant Temodar®." A recent study reported on over 100,000 glioblastoma patients and found that only half of them received any form of chemotherapy. There are situations where patients will not get your required treatments for many reasons. This restriction will cut off at least half of the eligible population – the half that would benefit the most by using Optune. Please remove this restriction.

4. "Must have a Karnofsky score of 70 or above." The Karnofsky scores are subjective and sometimes the score drops temporarily for reasons unrelated to treatment failure such as infections, dehydration, and seizures. If a patient is in such poor shape that they cannot use the device effectively it would be reflected in the compliance rate anyway. So this restriction could be dropped and the intention behind it would be taken up by the compliance restriction.

5. “Must use the device 18 hours a day.” It is very reasonable to discontinue the treatment if the patient is not using the device correctly. However, according to the most recent research, there is benefit when patients use it for at least 12 hours a day. So I would request the restriction be changed to “Must use the device for at least 12 hours a day” but allow exceptions for when there has to be a break in the treatment plan such as to allow time for a skin irritation to heal. But again, remove the restriction and leave the medical decision about when to stop up to the patient and the doctors.

6. “Must start within 7 weeks of end of chemo-radiation.” As mentioned above, not everybody has chemo-radiation. And for those that do, some patients develop complications that would require Optune to be delayed and some might not even learn about Optune in time. It is a very chaotic time in these patient’s lives and putting an artificial time limit on making such a life changing decision adds stress to what is already the most stressful time in the families’ lives. So please eliminate this restriction also.

And finally, the requirement for “benefiting from use between days 60-90” may be early to see the benefits. It has been shown that Optune is slow and steady and that most of the long term survivors had an apparent recurrence (pseudoprogression) early on but continued therapy and the tumors shrank. In the EF-14 trial, Optune was used through the first recurrence and stopped at the second recurrence. Since the LCD is pretty much based on this trial, you should follow the trials’ guidance in this respect. Please change the requirement to “benefiting from use by 3-6 months not weeks of use “or drop this restriction and allow the patient and the doctor to make the decision on when to stop.

Thank-you for allowing me to voice my opinion. I’m very impressed with the professionalism CMS has shown in handling this important issue in such an open, transparent manor taking into account the views of all interested parties while hopefully keeping the needs of the patients at the forefront.

Debra Parrish

Good morning. My name is Debbie Parrish and I represent the Medicare beneficiary who filed the policy challenge. I have represented numerous Medicare beneficiaries in the Medicare appeals process as they seek coverage for TTFT. Some of you are here today.

In the course of my representation, it has been my privilege to bear witness to many beautiful family expressions of love, support and determination to help their family manage this difficult diagnosis. Unfortunately, these beautiful family moments are thrown in stark contrast to the bureaucratic process that has delayed coverage of a treatment that has been the standard of care for the GBM community and now proposes restrictions that would preclude coverage for the vast majority of Medicare beneficiaries.

I learned that a request to reconsider this policy to bring it in line with national payer policies and practice guidelines was submitted last year. You can imagine how disturbed I was to learn that, in fact, that Medical Directors were told not to start that process last fall.

I hope we can all agree that we want the best health care for our family members and that we want a government that works for the people. It is difficult for me to understand how a government servant could believe that delaying revision and reconsideration of this policy was or is in the interest of Medicare beneficiaries.

It is also disturbing to know that this policy could be changed or retired at any time, and that this LCD is currently being used to block Medicare coverage of a life-saving treatment. Again, this slow walking of this change does not reflect a government that is working for the people.

Numerous Medical Directors from Medicare Advantage Plans have testified that but for this policy, they would be extending TTFT therapy to individuals that have a glioblastoma.

On Tuesday, I heard that there was a belief among the Medical Directors that there was not evidence to support coverage of TTFT until this past March. This is stunning! In 2018, there were multiple publications in JAMA (one of the most prestigious journals in our country). Second, it had a Level 1 NCCN designation. Very few treatments get that designation.

Third, you had statements in the publication saying this is the greatest break-through in the treatment of GBM.

Fourth, every major payer in our country has been covering TTFT for years.

There have been over 100 Medicare Administrative Law Judge decisions finding that TTFT meets Medicare coverage criteria. In rendering those decisions, Medicare judges have stated, "there is overwhelming evidence that TTFT is medically reasonable and necessary." "The LCD has not kept pace with the clinical and scientific development." "The LCD is noticeably outdated and ignores medically relevant data from the most prestigious medical institutions in the world, including medical opinions; research articles; peer reviewed studies; university research; clinical oncology reports."

I urge you to consider those statements and that evidence now and drop these restrictions. Although I welcome Medicare's move to explicit coverage (as late as it is), I'm concerned these restrictions reflect another strategy to deny access to this treatment. None of these restrictions exist with commercial payers.

First with respect to the NCI-designated cancer center, those centers are located around major cities in California and the Northeast. There are 14 states that do not have a single center. I'm from Miami which means if I got a GBM, I would have to drive 4 hours across Alligator Alley and back. That's four hours with a large bladder, a full tank of gas, and a lead foot. I think this restriction is unwarranted. Based on my experience, more than 80% of Medicare beneficiaries I have represented on that criteria alone, would not have Medicare coverage.

With respect to recurrence, the same study that supports coverage for newly diagnosed GBM included individuals who had a recurrence…the exact same study. It was disturbing to see that the contractor advisory committee was told not to consider evidence for recurrence.

Many Medicare beneficiaries cannot have surgery as we well know. I am unaware of any medical device that has a daily use restriction, let alone one with 18 hours a day.

Requiring that an NCI-designated center is inconsistent with the DME benefit which is to allow people to have care at their home.

I urge to immediately retire or revise this LCD so that people suffering with a GBM can have access to this treatment now. I urge you to drop restrictions 2-5 and modify 6-7 consistent with the literature and the consensus of experts.

Thank you.

Steven Welhoelter

I would like to thank the Committee for giving me and everyone participating in this forum the opportunity to help shape Medicare's policy on Optune.

Some of you may remember me from the CAC Committee meeting in March where I shared my experience of living with GBM and thriving with Optune.

In case you don't remember, my message was pretty simple. I was alive 5 years after being diagnosed, in large part, because I have been wearing Optune most of that time. As you can see, it is still working.

My experience along with the results of the Optune clinical trial, the FDA and NCCN approvals led me to ask the Advisory Committee why people on Medicare shouldn't have equal access to this proven therapy. After a lengthy deliberation, the Advisory Committee reached a consensus that Optune did in fact have the potential to extend the lives of Medicare patients.

With this endorsement, I felt that equal access and coverage for everyone was within reach. When the draft coverage was issued, I have to admit I was disappointed to see so many restrictions placed on patients seeking Medicare coverage. I asked myself why would they be held to a higher standard than what I was required to meet? I also wondered why the conditions for the use of Optune were different than that of surgery, radiation and various forms of chemo? Due to the complexity and the aggressiveness of GBM, shouldn't the decision on how, when and where to use the approved therapy be left up to the physicians and their patients?

In my opinion, the proposed policy has the potential to discourage Medicare patients and their doctors from considering Optune before they even have the opportunity to fully understand the risks and benefits.

An important question to ask is, what is the downside of removing these proposed restrictions and using the same standards applied to all other patients? Considering the prognosis for GBM patients, I suspect it will have little to no impact on the individual being treated.

Take as an example the requirement that a Medicare patient receive care at an NCI-designated facility. As you have already heard, this requirement appears to ignore the fact that thousands of people are already being treated at centers and facilities certified to prescribe Optune. In many cases, an NCI facility may not be reasonably accessible to people throughout the country. In my opinion, it makes no sense for a person on Medicare to bypass a center or a physician that has already successfully treated hundreds of patients. There is no doubt there will be extra expenses and higher stress occurred in having to travel longer distances to get to an NCI facility.

The real question is how does this requirement improve a patient's quality of life or the chance of living longer? I suspect there is none.

On a personal basis, in a year I will be Medicare-eligible. If this current proposal is adopted, I will be faced with the decision of having to leave my Neuro-Oncologist who has successfully treated me for 5 years and find a new one at an NCI facility across the state. This will require me to drive 4 hours to hopefully get to the same treatment that I have been receiving.

Many GBM patients will be faced with the same decision that I will have. Due to the additional hardship, some may choose not to pursue Optune or to continue its use. What would you do if you were in my situation?

I'd like to suggest that you make attending an NCI facility a recommendation rather than a requirement.

There are other conditions in the proposed policy that I believe infringe on a physician's ability to tailor the treatment to best meet the Medicare patient's needs. I believe most concerns have been communicated to the Committee in writing or have been highlighted during this meeting today.

These concerns need your attention to ensure the policy is benefitting the patient to the maximum possible extent. I implore you to listen and act upon the feedback from all these courageous patients and caregivers that are out there just trying to find a way to make it through another day. We need your help. Please don't make it harder than it already is. Thank you.

Colin Gerner

Good morning and thanks for sharing your stories. I'd like to talk with you today about my journey with my brother who was diagnosed with GBM in September 2017.

I have been sitting in the back of the room listening to everyone's stories and concerns. I applaud everyone for having the strength to talk about GBM. It is sometimes hard to talk about it, but it is real and so many are going through it.

I find it frustrating listening to all the areas of the proposed LCD that you have mentioned today. Looking around the room, I met Glenn in New York City a couple of months ago. I met Brian in New Orleans. I met Jimmy last night in the elevator.

These are real people. This is a real thing. They are all ferociously fighting GBM along with so many on the phone and my brother back home in New York City. Imagine looking them in the eye and telling them that they can't be treated because they don't live near a center. Imagine looking through a proposed LCD and saying 'I'm sorry I know you have been doing great for the last two years though you were only given 10 months, but we can't treat because of X, Y, or Z. You have to travel 10 hours away.' That's not possible for so many people. As if GBM weren't difficult enough already!

My brother was diagnosed at 27 years old after an unexpected seizure on Labor Day. Our lives changed forever on that fateful day, but my brother wakes up every day with the Optune cap on his head, a smile on his face and an absolute fire in his eyes. He is determined to become much, much more than a statistic and he has done that over the past 22 months.

There's been a lot of what ifs circulating over the last 22 months. What if he didn't have a seizure? What if no one was around when it happened? What if it wasn't the size of a golf ball?

What if he didn't have a recurrence? These are difficult, difficult what ifs but today I have learned a whole lot more what ifs that I never thought about until I sat in the back of this room.

I have heard so many people talk about the proposed LCD. What if, what if, what if? Well, what if these get approved? What if someone needs a treatment that is helping them? I credit so much of my brother's improvement to Optune. He just had an MRI last month and it was showing as clear after a recurrence. That's amazing but there are so many instances where there are harder what ifs.

I urge each of you to look at these what ifs on this proposed LCD and say what if this was your brother? What if you were 27 years old and you had to face this in the eyes? What if he was 65 years old? What would I do then? What if, what if, what if? Please think of all of these as you look forward to enacting them. I thank you all for your time today. Always live, stay strong.

Moderator – Thank you for all the first session speakers and commentators. We appreciate you being here. We'll be back after a break.

Jim Reilly

My name is Jim Reilly and I am an executive with the retail grocery industry and Chairman of the Board for the American Brain Tumor Association, and the son of a mother and mother-in-law who both battled a brain tumor diagnosis. My mother-in-law passed away from GBM.

Some of you may know the horrific impact of a GBM diagnosis firsthand. In all honesty, I hope you don't. To me, GBM is an unforgiving disease that has no boundaries. And with extremely limited treatment options available, it aggressively steals away your loved ones by breaking down their health and often the very essence of who they are.

It is unbelievable to me that the collective of brilliant scientists and researchers have yet to discover a way to combat this common enemy. It is understandable as brain tumor research continues to be under-funded and often overlooked. I do believe, however, that innovative discoveries are on the horizon. I am grateful for the discovery and FDA approval of TTFT proven to extend the life of a patient diagnosed with GBM.

As a former caregiver to my mother and mother-in-law, I can personally validate that the proposed LCD coverage criteria for TTFT would likely have a negative impact upon the patient and their access to life-extending care.

I currently live in Boise Idaho, a state without an NCI-designated cancer center. If my mother-in-law was alive when TTFT was approved by the FDA, I would have done everything within my power to ensure that she had access to the gift of living longer. This pursuit would not be without major implications affecting her and my family.

Living in Idaho, we do not have access to an NCI-designated cancer center. Given my mother-in-law's health following surgery, radiation and the side effects of those treatments and the disease, we would have been forced to drive 6-7 hours to Salt Lake City, Utah. An overnight stay would certainly be needed as would time off from my job. I assume return visits would be necessary, further burdening my mother with poor health, my mother-in-law with poor health and our family.

The proposed LCD coverage criteria for TTFT just does not make sense to me. Not only is it not required within the FDA label, but it makes me question whether the government believes only NCI-affiliated healthcare providers can deliver quality care.

This criteria is based without evidence and does not appear to recognize the health impact to an older adult diagnosed with GBM who has undergone extremely invasive treatment approaches.

On behalf of my mother-in-law and those who have lost their battles with GBM, please do not limit access to life-extending care by requiring older adults who are extremely sick and often financially limited to travel to designated cancer centers to receive life-extending care. It doesn't make sense and it doesn't seem to adhere to the Hippocratic Oath. I ask you; please do not inflict unnecessary burdens on this patient population. Give them a chance to live. Thank you very much.

Dr. Aaron Mammoser

My name is Aaron Mammoser and I am a Neuro-Oncologist at LSU in New Orleans. My background, I am a Fellowship trained Neuro-Oncologist trained at MD Anderson. I spent 6 years following Fellowship on Faculty at the University of Michigan before moving to LSU in New Orleans.

As my region's only Neuro-Oncologist, I can appreciate that Medicare patients with newly diagnosed GBM will now have coverage, but I have a significant concern that coverage depends on where they receive their care.

GBM patients can have a number of limitations affecting their ability to travel. Primary among those are physical limitations, however, practicing in Louisiana I can appreciate that the financial resources of many patients are quite limited. There is no NCI-designated cancer center within Louisiana and if you look in the surrounding states, patients would either have to go to MD Anderson in Houston or University of Alabama-Birmingham for their care.

As I mentioned, this is a significant burden on a patient's financial and physical resources. They often have limited means. I believe this restriction would exclude treatment of many of our poorer patients.

I also have concerns about the message that is being sent about our smaller centers. As I said, I practiced at an NCI- designated center previously and I have a great deal of experience with Optune. By limiting patient care to NCI centers, it sets up an advantage to these centers with respect to patient treatment and it also endangers the health of the smaller centers.

I would encourage that this restriction to NCI centers be revisited and revised. Thank you. I have no further comments.

Dr. Suriya Jeyapalan

I'm Suriya Jeyapalan and the Director of the Neuro-Oncology program at Tufts Medical Center in Boston Massachusetts.

I get the pleasure and the honor of being an investigator on both EF-11, which is the recurrent GBM TTFT trial published in 2011, and I was also an EF-14 investigator which is the current designation we are looking at with TTFT for newly diagnosed GBM.

I wanted to make a comment from an investigator's viewpoint. When the device was originally FDA approved for recurrent GBMs, there was some discussion about how effective it was in that setting because it was tested against chemotherapy or the physician's choice.

Unfortunately, as a lot of people in the audience are aware, for recurrent GBM there has never been an effective therapy that has been shown to work. When the device was shown to be just as good as anything out there, a lot of people took away from that trial that for as much good as we were doing with TTFT for recurring GBMs, you might as well just put some electrodes on their head and tell them to have a nice day.

To their credit, the company didn't follow along with that thinking. They then opened a trial with newly diagnosed GBMs. Their thinking was that there was a signal that was seen in the recurrent GBM population. They had a very difficult time treating that population. We have had more success with the newly diagnosed GBM patients. This is before the disease has had a chance to break through treatment and get out of control. They ran a very positive trial.

In that trial with the other investigators, less than 20% of the centers were NCI-designated centers. Over 80% of the centers were other cancer centers in the U.S. and worldwide that decided there was something in this technology that deserved a second chance, especially in a disease that is so hard to treat.

If we depended on NCI centers to open up this trial, it would not have opened. I trained and practiced in NCI cancer centers. Because of their low participation in the trial, they still feel that this device is not as effective as a lot of the other ones of us who have participated in the trial setting and in the commercial setting as well.

In Boston, I receive patients who come to me because they have heard about this treatment through websites, blogs, etc. but were not offered it at their initial treatment visit at other centers.

So, because of a lack of exposure to the device and understanding that it works and being familiar with it, by limiting it to centers that are not familiar with the device and not experienced with it, you are going to prevent it from being open to everybody. That does a disservice for all the investigators, such as myself. This was opened up to 80 medical centers worldwide. Sixty were in the U.S….all very good cancer centers. It is unfortunate it is now being restricted to centers that did participate in the trial are no longer going to be able to provide it to Medicare patients.

About 20% of the patients on the trial were older patients. These patients came to our centers, they wanted to be treated, the trial was positive. Now there seems to be some restriction to their being able to participate.

The other comment that I would make as an investigator is that they are restricting the use of the device to within 7 weeks of getting chemo and radiation. I have to say in my experience, some patients are very interested in the device upfront, but some patients need to think about it. It is a very novel treatment for cancer. The company is now 3 for 3 for FDA approval for the trials they have put forth. So, clearly something is happening not only in brain tumors but was recently FDA approved for mesothelioma. It takes time for people to understand what this technology is all about. Sometimes people take several months to make that decision and I don't think they should be penalized and refused treatment because they made that decision more than 7 weeks after completing chemo-radiation.

Another thing I would like to mention is they said the beneficiary will use the treatment for at least 18 hours a day. Some are able to do that, some are not.

(Moderator had to end discussion due to time constraints.)

Dr. Daniela Bota

I am board certified in Neurology and I have completed a Fellowship in Neuro-Oncology at Duke. For the past 12 years, I am the Director of UC/Irvine Neuro-Oncology program. I have a broad training in both Neurology and Oncology and for this year I have been conducting clinical trials for neurological malignancies through investigator initiated and from social funded studies. Before my residency, I completed a PHD in Molecular Biology and I concentrated my work on designing and conducting work for the screening and validation of promising anti-GBM drugs.

I am very supportive for the use of Novocure. I am quite concerned with some of the discussions that we had today. The recently announced LCD for Optune allows coverage for the patients with newly diagnosed GBM. But as another case for my patients, out of which I have treated thousands of people, I would like to request that the LCD be expanded to include Medicare beneficiaries with recurrent GBM.

You are aware of the data for newly diagnosed GBM or the TTFT for Temodar® were improving the long-term survival at 5 years compared to Temozolomide alone. It is equally important to remind you of the benefit of TTFT as monotherapy for recurrent GBM. I have many elderly patients and the number is going higher and higher every day. They have multiple comorbidities and they have limited ability to tolerate chemotherapy especially in the recurrent setting, same for radiation and for their surgery. Published evidence shows Optune offers those patients the same overall survival as chemotherapy without the side effects and the toxicity.

To date I have prescribed Optune for more 50 patients with recurrent GBM. They had good tolerance for the therapy. They have exhibited very few side effects, actually much less than what we usually see with chemotherapy. And, they benefitted from an improved quality of life. Clinically these patients had a remarkably similar response to treatment as those that received chemotherapy. I have to say that some of the patients had even better responses and for longer periods of time.

I don't want to take more of your time. I am calling from an international line because this is extremely important for me. I do applaud your efforts in reviewing the data for Optune for Medicare beneficiaries. I hope you will issue a proposed positive coverage determination for newly diagnosed GBM. But please, I am still concerned that there are still very few treatment options for recurrent patients. As you heard, there is still an overwhelming need in our field.

I strongly urge you to revise your draft policy and include TTFT for recurrent GBM. Thank you so much.

Dr. Steven Toms

I'm a Neuro-Surgeon Oncologist, so a brain tumor surgeon who has spent over 30 years doing research on GBM, including basic science research, drug delivery technology advances as well as clinical trials. I was a participant on the EF-14 trial and I enrolled several patients in theEF-11 trial when I was at Cleveland Clinic. I have had 20 years of surgical practice. About 80% of my practice has been brain tumor. I have cared for over 1,000 GBM patients in my career at Vanderbilt, Cleveland Clinic, 10 years at Geisinger and that last 2 years at Brown University in Providence.

I would like to reiterate some of the remarks Dr. Jeyapalan was presenting about the NCI-designated cancer center requirement of the LCD. For example, here at Brown I would not be able to treat Medicare patients even though I have enrolled many patients on Optune both commercially and during the trials. My patients would have to travel an hour to an hour and a half to Boston to be able to enroll. This is a significant burden for the elderly population we care for in Rhode Island, which has one of the highest rates of GBM in the country.

Similarly, when I was at Geisinger for 10 years, we cared for over 600 GBM patients in mostly rural Pennsylvania. If this requirement had been in place for our Medicare population, they would have had to travel 2-4 hours to go to either New York City or Philadelphia. Often the centers (such as Fox Chase), which did not have a comprehensive brain tumor group even though by this criteria, they would have been allowed to prescribe.

I think there is a bit of an artificial designation here between an NCI cancer center, which is certainly a badge of expertise in cancer in general but does not necessarily mean that those groups have great expertise in brain tumors. As Dr. Jeyapalan pointed out, the teams in Boston (the only regional NCI cancer center for New England) had very little experience in prescribing this particular device for GBM.

In the time I have remaining I would like to comment briefly about the 18-hour requirement of wearing the device. As many of our patients, advocates and physicians have described, 18 hours or more is ideal. However, I recently completed an analysis of the EF-14 data suggesting that every decile improvement over 50% wear time, (so anywhere from 12 hours to a maximum of up to 22 hours per day), we saw improvements in survival.

Although 18 hours is certainly a goal and we advocate that but having that as an absolute burden would be very difficult for many of our elderly patients or if they get complications from the device, which mostly consists of skin breakdown or sores requiring time off from the device or moving the electrodes.

The other issue with that portion of the LCD is who would be responsible for this? If someone comes in at 17 hours for one month, do they lose coverage? How that is going to be enforced universally is a difficult proposition in continuing to understand who is going to be eligible for coverage under the current rules.

Lastly, I would like to echo what my clinical colleagues have suggested that in both the EF-11 trial and clinical experience suggests that this device has utility in recurrent GBM and in many of our upfront or de novo GBMs who sometimes aren't ready to make a decision on Novocure (the tumor treating field treatment) within that first 7 weeks. Sometimes they need more time to think, sometimes they are looking at other clinical trials or sometimes they are either too fatigued or elderly or having difficulty with the Temodar® and just not ready to begin their second phase of trial. I would encourage the group to consider aggregating the requirement to start treamement with TTFT within that 7-week period.

I thank the group for considering expanding coverage to our Medicare patients with GBM and would ask the Committee to consider somewhat loosening some of the requirements in the LCD to make TTFT more eligible in a more practical manner for more of our patients. Thank you again for your time. I appreciate your efforts.

Dr. Ashley Sumrall

Thank you for the opportunity to comment on the proposed LCD for TTFT for newly diagnosed GBM patients. I am pleased to see that some of my Medicare patients will now have access to this technology without having to go through a multi-year process of appealing denied claims. It is my hope that you and your colleagues will consider some modifications to these proposed

criteria in order to ensure consistency and access to this important treatment option and to remove unnecessary barriers to coverage.

I am a Neuro-Oncologist and Medical Oncologist at the Levine Cancer Institute in Charlotte, North Carolina. I treat patients with GBM every single day. This is a very tough disease. We need every tool available to help patients achieve their treatment goals.

TTFT is first treatment option in over a decade to show an extension in overall survival and progression-free survival for patients with newly diagnosed GBM. I offer Optune to my patients with newly diagnosed as well as recurrent GBM. The ideal patient for this therapy is one who is motivated, who wants aggressive treatment, has a good performance status and has a support system in the home.

The current proposed draft will limit access for patients with recurrent GBM. I ask the MACs to reconsider their blanket non-coverage of recurrent GBM as many elderly patients would benefit from Optune in their current setting, especially those who may not be able to tolerate chemotherapy. In my clinical practice, I've seen patients achieve good outcomes from the treatment who are both newly diagnosed and recurrent GBM patients.

I really don't understand the clinical rationale requiring a Medicare beneficiary to receive a prescription from an NCI cancer center in order to receive coverage for a therapy that has been deemed safe enough to use at home. The nearest NCI facilities are 1-1/2 to 2 hours from Charlotte and the distance would create significant hardships for my Medicare patients with no medical justification. I am concerned that this will set up a system where some patients are granted access to approved options and others are not. In a disease with so few approved options, why would we want to create further obstacles? Please remove this site of care restriction so that all Medicare beneficiaries who are battling GBM can access all FDA approved therapies.

Another requirement I think should be amended is that a Medicare patient should achieve a daily usage of 18 hours per day in order to receive coverage. While the data shows that patients have better outcomes the more they use the therapy, the literature supports that patients utilizing Optune at least 12 hours per day achieved a statistically significant extension in progression-free as well as overall survival compared to Temozolomide or chemotherapy alone. This requirement should be amended to 12 hours per day, or preferably removed completely.

Furthermore, the MACs are proposing that Medicare patients must start treatment within 7 weeks post chemo/radiation in order to receive coverage. There are many reasons why a patient may not be able to start treatment within that 7-week window. One such issue may be participation in a clinical trial, or they could need more time to heal post-surgery or radiation. No commercial insurance coverage policies impose this requirement.

The Medicare program should allow access to patients without an arbitrary limit on when patients can start Optune.

In closing, I want to thank you for the opportunity to share my views on what I feel is an important matter. My patients with commercial insurance have had access to this therapy for many years. I hope the MACs will finalize this policy with the proposed modifications without further delay. Thank you.

Dr. Nicholas Avgeropoulos

Thank you for the opportunity to talk today. I am going to echo a lot of the sentiments of previous speakers.

My name is Dr. Nicholas Avgeropoulos. I am the Co- Director of the Brain and Spine Tumor program at Orlando Health and UF Cancer Center here in Florida. This is not an NCI-designated cancer center. We did enroll patients in the EF-14 study including a patient who will be speaking as a beneficiary later in your program today. I don't know that the other therapies we had been giving had been working and this did.

I am a Neuro-Oncologist by training, board certified in neurology and Neuro-Oncology. Patients with GBM present a significant treatment challenge. We have very few options. I have been practicing for over 20 years and am right in the trenches every single day seeing patients with GBM. I have been involved in opening multiple investigator studies, pharmaceutical and other

corporate studies and am part of a consortium, including an NCI consortium trying to find alternatives for these patients with no set cure.

The research studies included the EF-14 study and I do have several points that I would like to reiterate that were brought up earlier but are also are important from my perspective.

First, I would echo Dr. Sumrall's comments about the expansion of the indication not only for upfront use but also for recurrent progressive GBM. We have seen complete responses with utilization of the device alone. Sometimes that takes 8-10 months to take effect. As opposed to other therapies that might have a more robust wow effect in terms of imaging, this may be a therapy that may be the tortoise approach to a multi-disciplinary approach to tumor control that can really help in the long run. It does require behavioral modification on behalf of the patient and their advocates but nevertheless, it is a therapy that has proved to work with the data in all the publications.

The other issue I would like to bring up is that TTFT be initiated within 7 weeks. There are many reasons for delays that can occur including wound healing as mentioned, and various other logistical issues (scheduling, hospitalization, etc.). I think this would be wrong to delay that.

Limiting this to patients that have seen NCI-designated cancer centers I think is not in the best interest of the patients for several reasons. There is only one in Florida and travelling there would incur a lot of cost and scheduling issues and would overburden NCI institutions for simple Optune prescriptions, at least from my perspective. Optune is a therapy which is easy and is delivered at home and doesn't interfere with the running of the clinic for the most part.

Being a speaker on the Novocure board, I have the opportunity to go around the country to see how people utilize this device. Whether it is Radiation/Oncologists or Neuro-Surgeons, Medical Oncologists or Medical Neuro-Oncologists prescribing…taking away the grass roots ability to deliver treatment close to home and then centralizing it without really a good reason that I can see, I think would be a disservice to patients.

Restricting patients to 18 hours per day (wearing the device), there are other treatments we have to consider. If patients are able to stick around on the device for over 50%, I think it is a good idea. If there is an audit that shows the person dips below the 18 hours (75% compliance), there is a loss of coverage. I think that would be unnecessarily punitive. Sometimes there is scalp needs to breathe and heal. Sometimes the patient just needs to take an emotional break, or are hospitalized and must take the device off, or for other medical interventions that are required for the device to be off for a little while.

(Moderator stops speaker due to time constraints.)

Dr. Eric Wong

I am a staff a Neuro-Oncologist at Beth Israel Deaconess Medical Center In addition to being a Neuro-Oncologist; I serve on the CAC in the JK Jurisdiction representing oncologists in the State of Massachusetts. For disclosure purposes, I receive research grants from Novocure, the manufacturer of Optune.

I have a number of issues concerning this LCD. First, I would like some clarification on why this LCD was formulated outside of the usual CAC structure. When I looked at the roster, there are a lot of names that I do not recognize from the Neuro-Oncology community.

I speculate that the Committee wanted to preserve the objectivity of the panel, but on the other hand, there are a lot of nuances when treating patients with GBM. I think it is probably best for the Committee to have someone who has a lot of experience with this device. Yes, we want individuals with objectivity, but we also need practitioners with real world experience who can understand the nuances of treatment in this population of patients.

The second issue for which I would like to have some clarification is why the treatment requires the patient to travel to NCI-designated facilities. I think this is a little bit restrictive, if not discriminative.

There are patients who are already struggling with travel issues, even in big cities. In states with sparsely populated populations or in rural areas and even on Indian reservations you are requiring patients to travel to NCI-designated facilities. Most of the U.S cancer patients are treated by their local oncologists. You are really causing problems in having patients who are

economically disadvantaged to travel to an NCI-designated facility. Unless the facilities provide free transportation, this is not going to work. You are just excluding a number of the population.

The third issue I have with the policy has to do with recurrent GBM. I do understand that by the time patients develop recurrent GBM; their survival time is going to be short. I have treated a number of patients with newly diagnosed and recurrent GBM. There are sub-populations who may benefit from this therapy. They are primarily patients that have smaller tumors, good performance status and who have good family support.

I think a blanket non-coverage policy for recurrent GBM is not warranted. I do think that when it is covering the recurrent GBM population, we need a tighter policy probably restricting to those with good performance status.

Here are my free comments and I also wrote a long, detailed letter to the Committee voicing my concerns about the LCD. Thank you very much for giving me this opportunity.

Justin Kelly

Good morning. I would start by noting that my comments today are on behalf of the more than 1,700 Americans who are using TTFT to treat GBM (the deadliest form of primary brain cancer), and the scientists and physicians who led the development of this therapy over the past 19 years.

It was one year ago today that we filed a Reconsideration Request for Medicare's negative LCD for TTFT. Our request was simple. We asked that Medicare provide coverage for TTFT that is consistent with the FDA approved labelling and indications for therapy. We thought the request pretty clearly met the Medicare standard for providing coverage for treatments that are reasonable and necessary. The FDA approval after all was based on the review of the clinical data from a large, successful, randomized trial with GBM patients…the largest ever completed successfully.

The data showed that combining TTFT with maintenance Temozolomide treatment resulted in a statistically significant increase in patient survival compared to treatment with maintenance Temozolomide alone, without any side effects that reduced quality of life.

The contractors that administer the DME benefit (CGS and Noridian) which are subsidiaries or affiliates of Blue Cross/Blue Shield of South Carolina, and Blue Cross/Blue Shield of North Dakota respectively, have instead proposed to restrict access to a therapy that only a small fraction of patients for whom the FDA believes there is reasonable assurance that the treatment would extend survival.

We are here today to repeat our simple request. We ask that Medicare cover TTFT in accordance with the FDA approved indications for use. We therefore object to the LCD proposed by CGS and Noridian on procedural, substantive and pure common-sense grounds.

I will start with the procedural failures in developing the current policy. In the interest of time, we will note the most material procedural issues and how CGS and Noridian have developed this proposed coverage policy.

As I mentioned, we filed a Reconsideration Request on the LCD on June 20, 2018. The DME MACs were required to notify us of their final determination by September 18, 2018 and confirm this in writing to us. Under the Medicare Program Integrity Manual in effect at the time, this deadline was missed without explanation. Medicare then issued a new Program Integrity Manual revision on October 3, 2018, which required several substantial delays in the process of completing Reconsiderations of coverage policies. On October 11, 2018, the DME MACs notified us that the new guidance on Reconsideration of LCDs would be applied retroactively to our request for coverage.

This October 2018 guidance has already been rescinded entirely and revised three times, each time more closely resembling the actual coverage process being followed by CGS/Noridian's LCD Reconsideration. By contrast, the same manual was not revised from 2015-2018. We think it is reasonable to ask the question whether this guidance document was rushed out in order to be applied retroactively to slow the process of granting coverage of TTFT. Finally, we note that CGS and Noridian (also as Medicare Administrative Contractors or MACs), have clear authority to revise the coverage policy today without additional delay.

The incredibly clear language included in the currently effective Program Integrity Manual (Chapter 13.3), “MACs have the discretion to revise and retire LCDs at any time on their own initiative.” We urge CGS and Noridian to stop delaying coverage for TTFT.

I will now address the substantive manner in which the proposed coverage policy fails to provide any evidence to support the limitations of coverage for TTFT.

The TTFT coverage policy proposed by CGS and Noridian imposes 7 conditions that significantly limit access to TTFT. We note that the Medicare Program Integrity Manual (Chapter 13.5.3) specifically states that CGS and Noridian must rely on ‘peer review medical journals, systematic reviews, META analyses, evidence-based statements and clinical guidelines when limiting coverage.’ After reviewing the Bibliography attached to the proposed LCD, we cannot find evidence that justifies coverage restrictions 2-7.

LCD restriction #2 – My fellow commenters have shared their perspective and we concur. Patients should be allowed to access this therapy after biopsy only to confirm diagnosis.

LCD restriction #3 - My fellow commenters have shared their perspective and we concur. This restriction should be removed completely.

Regarding the requirement for NCI-designated cancer centers. My fellow commenters have shared their concerns and we concur. This restriction should be removed. The better approach in our view is to follow the FDA requirement that prescribing physicians have received training and certification from the manufacturer.

LCD restriction #5 - We concur with our fellow commenters. The restriction is contrary to clinical data that supported the FDA approval and should be removed.

LCD restriction #6 – Limit access to patients with a Karnofsky score of at least 70. The primary clinical guidelines indicate that threshold should be a score of 60. This restriction should be removed or at least lowered to a threshold of 60.

LCD restriction #7 - My fellow commenters have shared their concerns and we concur. This restriction should be removed or replaced with a requirement for an average of 50% compliance with therapy over a 3-month period of time.

Finally, I would like to close with a common sense perspective on this coverage policy proposed by CGS and Noridian. The vast majority of all private healthcare payers provide coverage for this therapy. None of these payers have attempted to impose these restrictions that CGS or Noridian are proposing. Moreover, your parent corporations and affiliates have positive coverage for TTFT that are less restrictive than what we are discussing today.

In closing, we strongly encourage CGS and Noridian to issue a revised LCD for TTFT that is consistent with FDA approved indications for use without further restrictions and without further delays. Thank you.

Moderator – Thank you Justin and now we are going to turn it over to Dr. Gurk.

Dr. Peter Gurk

Thank you all for your attendance today here, for your input, and for your interest on this Medicare policy.

Again, I would remind all of you who made oral comments today please submit those comments to TTFTLCDComments@cgsadmin.com. Remember that the comment period closes on Monday, June 24, at 5:00 p.m. Eastern time.

Following today, the DME MACs, my colleagues and I will consider your oral and written comments and information that was presented today. Then, we will consider the proposed LCD and any changes to be made based on the comments provided.

The DME MACs will then post the final LCD on our websites and distribute links to that via ListServ. The final LCD will take effect minimum of 45 days following posting of the final LCD.

Once again, we thank you all your attendance today.