

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, PhD, RTI International

Good afternoon. Thank you for joining us today for the CMS Medicare Drug Price Negotiation Program town hall. I am **[Moderator]** from RTI International, and I will be the moderator for the town hall today. If you would like to listen to this town hall in Spanish, please follow the directions for accessing the Spanish line that appear on the screen. We will also have sign language interpretation throughout the town hall.

Welcome and Overview

Moderator, PhD, RTI International

To start us off, I will share a brief introductory video from Dr. Oz, the administrator for CMS.

00:04:08

Dr. Mehmet Oz, Administrator for the Centers for Medicare & Medicaid Services

Hi, everyone. I'm Dr. Mehmet Oz.

I'm the Administrator for the Centers for Medicare & Medicaid Services, also known as CMS. CMS is the Federal agency that oversees Medicare, which provides health care coverage for more than 69 million older Americans and people with disabilities. We also oversee the Medicaid program and the Health Insurance Marketplaces.

I wish I could join you today in person, but I want you to know I am eager to hear your feedback and am deeply grateful for your participation in today's discussion.

It is a crucial conversation.

No one in America should have to choose between buying groceries or paying for their medications. But many are forced to make this choice. It's a choice that comes with a personal cost in addition to a financial cost. I started my health care career as a cardiothoracic surgeon. So I know firsthand what happens when people can't get their medicine, like the ones that lower their cholesterol or blood pressure. Left unmanaged, these conditions can be dangerous.

CMS is doing incredible work reigning in the skyrocketing cost of prescription medications, and we need all of you to help us make real, lasting change.

Right now, we're working on the latest cycle of Medicare drug price negotiation.

We announced the drugs selected for this round earlier this year. Some of them are covered under Medicare Part D, and others are payable under Medicare Part B. For every drug, our priority is to reach an agreement with the manufacturer on a fair price for Medicare.

We are committed to being fair and transparent throughout the negotiation process. And that's where you all come in.

It's my goal to get input from people across the health care ecosystem. We want to hear your perspective about the drugs selected for the current cycle of negotiation and renegotiation.

Your input makes a difference – a big one. Thank you for taking the time to join us today. I'll turn it over now to our event moderator.

00:06:09

Moderator, PhD, RTI International

The town hall meeting today and tomorrow has a morning and afternoon session. For this afternoon session, we will hear from speakers on four drugs in the order you see listed here.

The goal of the town hall is to provide an opportunity for clinicians, researchers, and other interested parties to share input focused on the clinical considerations related to the drugs selected for the current cycle of negotiation and renegotiation. CMS will use the information shared during the town hall meeting to better understand clinicians' experiences prescribing or managing treatment with the selected drugs or therapeutic alternatives, and clinicians' considerations that drive treatment choice between the selected drugs and therapeutic alternatives.

In addition to the town hall meeting, CMS hosted private, patient-focused roundtable events, one for each drug selected for negotiation and renegotiation. Each roundtable event was open to patients, patient advocacy organizations, and caregivers. CMS will use the information shared during the roundtable events to better understand patients' experiences with the conditions and diseases treated by the selected drugs, and patients' experiences with the selected drugs themselves.

The information shared during both the town hall meeting and the roundtable events will also inform CMS' identification of therapeutic alternatives, key outcomes, and holistic adjustment of the starting point to develop the initial offer in negotiating with manufacturers of selected drugs.

The speakers at today's town hall meeting may include clinicians, researchers, patient advocates, patients, and caregivers. The number of speakers for each selected drug varies based on how many speakers registered to speak for each of those drugs.

This meeting is being livestreamed. Participation is voluntary, and speakers acknowledged and agreed by participating in the meeting that any information provided, including individually identifiable health information and personally identifiable information, will be made public during the meeting through a livestream broadcast.

This event is also being recorded. Recordings will only be used for internal program documentation and to produce redacted materials for public release, consistent with Federal privacy guidelines. By participating, speakers consent to being recorded for these purposes.

Clinicians should be mindful of their obligations under HIPAA [Health Insurance Portability and Accountability Act] and other privacy laws. CMS intends to make a redacted version of the transcript for the meeting available after all the events have ended.

Speakers were asked to disclose any potential conflicts of interest with the drug they are speaking about. As I introduce each speaker, I will note, and you will see on the slide, any disclosed potential conflicts of interest.

To accommodate as many speakers as possible, each speaker will be limited to four minutes for their remarks. There will be time for a brief follow-up after each set of speakers. I appreciate

speakers sticking to these time limits so that we are able to hear from everyone present. I note that the town hall meeting may end before the scheduled time, depending on the number of speakers.

The first three speakers will share remarks about Kisqali. Kisqali is commonly used to treat hormone-sensitive early breast cancer and hormone-sensitive metastatic breast cancer. The first speaker is **[Speaker 1]**. This speaker disclosed a potential conflict of interest, as shown on the screen.

Speaker Remarks for Kisqali

00:10:29

Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and representative of a patient advocacy organization)

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Good afternoon, my name is **[Speaker 1]**. I'm the **[Redacted]** for the American Cancer Society. I'm also an oncologist. I'm representing both the American Cancer Society and the ACS Cancer Action Network. We advocate on behalf of cancer patients, caregivers, families, and survivors.

I'm pleased to be here today to share the views of a subset of cancer patients who use the oncology drug Kisqali, as well as patients who take the other three cancer medications on the Medicare negotiation list. Cancer patients rely on oncology medications to both treat their cancer and prevent recurrence. As an oncologist, I've seen firsthand what a difference effective treatments can make in the lives of cancer patients. Kisqali, in particular, has extended the lives of many patients, giving them more time with their families, many of whom have young children.

Affordability of oncology therapies remains a serious obstacle for many cancer patients, and the risk of cancer increases with age, so Medicare coverage of cancer therapies is critical. It's critical that along with lowering costs, the development of new therapies and access to these treatments not be impeded in any way.

I'd like to share some results of a survey that we've done of cancer patients' experiences with drugs on the negotiation list. Working with Magnolia Innovation, ACS Cancer Action Network has surveyed 137 patients taking the four drugs on the negotiation list. For patients taking Kisqali, the most important factors in considering this medication as a therapy were quality of life, impact on

survival, and cost. In terms of their overall experience taking the medication, 70%, meaning 21 of the 30 patients, say that Kisqali was very important or critically essential as the only effective therapy for managing their cancer. Ninety-seven percent, meaning 29 of 30 patients, said that Kisqali made their daily life much better. Ninety-three percent, 28 of 30 patients, said that Kisqali had a significant positive impact on their emotional or mental well-being. Patients taking the other cancer therapies on the negotiation list had similar experiences. Across all four cancer drugs, patient-reported overall quality of life was much better while on these therapies, and 97% reported that their specific selected therapy had a significant positive impact on their emotional and mental well-being. Patients identified several types of delays and barriers to access, including utilization management by payers, for example, step therapy or prior authorization, and high out-of-pocket costs.

On affordability, at least 7% of patients taking each of the four drugs reported skipping doses, taking a partial dose, or not picking up their prescription due to cost. Cost was ranked among the top three important factors for all selected drugs included in the research.

In conclusion, we're making significant strides in the battle against cancer, and access to new and affordable treatments is paramount. ACS and ACS Cancer Action Network believe that the Medicare Negotiation Program can, if administered thoughtfully, help to lower costs for cancer patients. We appreciate CMS working with the patient community to understand the impact of the program and look forward to continuing work with you. Thank you.

00:14:55

Moderator, PhD, RTI International

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker has indicated that there is no conflict of interest.

00:15:11

Speaker 2 (registered as a representative of a patient advocacy organization)

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Good afternoon and thank you for having me. My name is **[Speaker 2]**, and I am appearing today as a patient advocate with an organization called Patients for Affordable Drugs. We unite and mobilize



patients in pushing for policies to lower the cost of prescription drugs in the United States. We seek the most systemic and structural solutions to the drug pricing crisis and are proud supporters of the Medicare negotiation mechanism.

In addition to connecting patients to speak with journalists and lawmakers, we collect stories from patients all across the United States who cannot afford their medications, and sadly, we have nearly 40,000. I will share two today about Kisqali.

[Redacted] from Kansas describes her experience in the following terms, “I have breast cancer again. I had been 17 years cancer-free in January 2025 when I was re-diagnosed with cancer once more, along with vision issues in my right eye. With everything, I had a hard time keeping up. I told my doctors that I could not afford the medicine and everything else. So, they got me help through my insurance specialty pharmacy to help pay for my medicine, and also through the Cancer Association to help pay for some of my costs, like rent and utilities. Even with all the help, it is still hard to keep up with all sorts of medical bills and medication costs.”

[Redacted] from South Carolina shares, “I was diagnosed with Stage IV cancer in my bones and breasts in June 2025. Kisqali is \$20,000 for 20 days every month. I can’t afford it. My oncologist won’t do anything else for me, so I am getting no treatment at all. Insurance will not cover it. They have a deductible that is over \$10,000. That’s my part, along with monthly premiums of almost \$1,300. I can’t afford that either. I have two small children at home and a retired spouse. I have to work six days a week to keep my home going.”

Sadly, these experiences are not atypical. One in three Americans report struggling to afford their medications. And a recent KFF [Kaiser Family Foundation] Health News article described how roughly half of cancer survivors carry medical debt. Medicare negotiation is desperately needed, as are continued reforms. Drugs don’t work if people can’t afford them. Thank you.

00:17:45

Moderator, PhD, RTI International

Thank you for your remarks. The third speaker is **[Speaker 3]**. This speaker has indicated that there is no conflict of interest.

00:18:04

Speaker 3 (registered as a health care professional)

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My name is [**Speaker 3**]. I’m a board-certified medical oncologist and a hematologist. I practice in a community-based cancer clinic in southwest Iowa. I treat various types and stages of breast cancer in my clinic. I’ll talk briefly about the usage of ribociclib, or Kisqali, in a specific type of breast cancer patients in two different clinical scenarios.

These drugs are generally called CDK4/6 [cyclin-dependent kinases 4 and 6] inhibitors and are only indicated in hormone receptor-positive and HER2/neu [Human Epidermal growth factor Receptor 2 neuroglioblastoma-derived gene] epidermal growth factor receptor negative types of breast cancer. These drugs are in pill form and avoid treatment with IV [intravenous] chemotherapy, which impacts less adverse effects and better quality of life in patients.

The first group I’m going to talk about is early-stage and high-risk hormone receptor positive and HER2/neu negative breast cancer patients. Here, the treatment goal is cure after a curative surgery. And in a Phase III clinical trial, Kisqali has shown invasive disease-free survival benefit when combined with aromatase inhibitor in high-risk Stage II and III breast cancer. In this study, a broader population were included even without lymph node–positive disease, and lower dose of drug has been used as well, as compared to higher doses used in advanced or metastatic disease.

There are alternative drugs available, like abemaciclib or Verzenio, which is also a CDK4/6 inhibitor, shown to have a benefit in this adjuvant setting, but these are studied in lymph node–positive, high-risk early-stage disease, and a daily dosing. The other drug, which has an intermittent dosing, three weeks on and one week off. And the other drug has a short duration of therapy, two years as compared to Kisqali for three years. But the side effects profiles are a little different. There’s diarrhea and interstitial lung disease and venous thromboembolism could be a side effect in the other drug.

In conclusion, Kisqali has a broader eligible population, including lymph node–negative patients with high-risk features in early high-risk disease, less diarrhea, and lower relative dose. But at the same time, ribociclib can cause abnormal liver function test abnormalities, and QTc [corrected Q



wave and T wave interval] prolongation-causing arrhythmias, and therefore may be less preferred for some patients with heart disease.

The second scenario I'm talking about is metastatic disease, or Stage IV hormone receptor positive and HER2/neu negative breast cancer. Ribociclib is the only CDK4/6 inhibitor demonstrated statistically significant overall survival benefit across all the three clinical trials, regardless of their menopausal status, endocrine therapy partner, or line of therapy. This drug is in the NCCN [National Comprehensive Cancer Network] Category 1 for the first-line therapy for metastatic hormone receptor-positive and HER2/neu negative breast cancer. The other alternative in this clinical scenario is abemaciclib or palbociclib. These are generally compatible in the second-line setting in combination with aromatase inhibitor therapy as well.

At times, tolerance and other adverse effects determine the choice of drug. In the absence of head-to-head data, selection between all these three drugs in the metastatic setting should be guided by usually first line in the NCCN category is ribociclib with the overall survival evidence.

I conclude with this. Affordability by lowering the cost and access to drug is important in both early-stage, high-risk, high-risk breast cancer, as well as in metastatic breast cancer. Thank you.

00:22:34

Moderator, PhD, RTI International

Thank you for your remarks and thank you all for sharing your experiences and perspectives about Kisqali. I have one follow-up question. What other information or evidence do you think CMS should consider in the evaluation of Kisqali? Please raise your hand to respond. **[Speaker 3]**?

00:23:01

Speaker 3 (registered as a health care professional)

I would say both. There are similar drugs around there, but they have their own perspective. Kisqali, a certain subset of population of patients would definitely benefit from Kisqali, and there may be some contraindication for Kisqali, and abemaciclib could be the other option in this setting. Both these drugs are very important drugs, and they have made a big impact in the metastatic and early-stage breast cancer with the survival, with the adverse effects, and the quality of life.

Speaker Remarks for Verzenio

00:23:41

Moderator, PhD, RTI International

Thank you. We will move on now to Verzenio with two speakers. Verzenio is commonly used to treat hormone-sensitive early breast cancer and hormone-sensitive metastatic breast cancer.

The first speaker is **[Speaker 1]**. This speaker has indicated that there is no conflict of interest.

00:24:09

Speaker 1 (registered as a representative of a patient advocacy organization)

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Good afternoon. My name is **[Speaker 1]**. I am **[Redacted]** for the National Minority Quality Forum. The National Minority Quality Forum, or NMQF, is a 501(c)(3) not-for-profit research and advocacy organization based in Washington D.C.

NMQF believes that health care policies should be designed to deliver direct, observable benefits that enable accountability and adhere to principles that align resource allocation with population health needs. Therefore, NMQF supports policy and regulatory constructs which serve to establish patient risk reduction as the fundamental metric for health care policy evaluation.

Government price controls do not meet that benchmark. Indeed, they risk disrupting market-driven incentives that contribute to innovation and increase the availability of treatment options that enable greater therapeutic precision and measurable and sustainable improvements in population health.

Breast cancer is the most common malignancy diagnosed in women worldwide with greater than 1.3 million cases and 450,000 deaths each year. The majority of HR-positive breast cancers are HER2-negative. Therefore, early-stage HR-positive, HER2-negative breast cancer is a significant public health issue.

Verzenio, the subject of my remarks, is a targeted CDK4/6 inhibitor used to treat HR-positive, HER2-negative breast cancer, particularly in high-risk, early-stage, or metastatic scenarios. Significant disparities exist. White women have the highest incidence, 75.5%, while Black women have a 19% higher mortality rate, more aggressive, higher-stage tumors at diagnosis, lower rates of endocrine therapy initiation, and higher recurrence risks.

According to the journal *Oncology Practice Management*, despite lower incidence, Black women with HR-positive, HER2-negative cancer have lower five-year overall and relapse-free survival compared to white women. Black women are more likely to present with higher stage tumors within the HR-positive, HER2-negative subtype.



In other words, a range of effective therapeutic options must be available. In closing, the National Minority Quality Forum requests that Verzenio not be subjected to the Medicare Drug Price Negotiation Program for initial price applicability year 2028 or subsequent years. Thank you.

00:27:29

Moderator, PhD, RTI International

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker has indicated that there is no conflict of interest.

00:27:41

Speaker 2 (registered as a representative of a patient advocacy organization and patient)

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Hi, my name is **[Speaker 2]**, and I want to thank you all for having me today. I come to you, and I speak as a patient and a patient advocate, working with the Tigerlily Foundation.

A little bit about my history is I was initially diagnosed in 2015 with Stage II hormone-positive, HER2-negative breast cancer. I went through the typical treatment, had a few setbacks, but I went through surgeries, chemotherapy, and then, in addition to some other medications, was put on an aromatase inhibitor, tamoxifen.

Fast forward to 2022, my cancer resurfaced, and I was staged metastatic, or Stage IV, with the cancer now spreading to several different areas of my body. When I was faced with the diagnosis again, my first thought was, if I have to go through chemotherapy again, I don't know that I'll choose treatment. It was that bad. It did prolong my life, and I am grateful, but it was a grueling experience.

When the doctor came to me with a treatment plan and named Verzenio, along with hormonal treatment, it was a game changer for me. Verzenio gave me the opportunity to receive targeted therapy to my cancer cells. It spares the healthy cells in my body that sometimes chemotherapy will also attack. Not only did I have the ability to not be on chemotherapy, which means that I have more time I'm not tied to a chair however often each week, I don't have to burden family members to take me to appointments. Verzenio gives me the autonomy that I need in my life. I'm able to take the medication at home and I can go to the doctor's office periodically to be monitored.

Time is very important, because time is something that I'm fighting against. Whatever time that I can use to spend with my family, to work, to do the things that I enjoy in life, I can't put a price tag on that.

It also saves money. I'm in a rural community, and it takes me an hour and a half one way just to get to my doctor's office and to the hospital. That saves gas. Instead of spending an entire day on an appointment, I'm able to save that time and money that it takes to get to the office.

The side effects are milder because it is in the oral form, so that is also a positive impact for me, and my quality of life is so important to me now. I'm very grateful for the extra time that I'm allotted because of this medication that I can spend with my two children and not be subjected to the bed because I'm not able to function. I'm able to attend school events and sporting events and this evening, I'm going to a band concert, and I'm just so grateful that my quality of life is much better with this round of treatment.

But there are some cons. There are side effects with Verzenio, a lot of gastrointestinal upset, diarrhea, and fatigue, and cost is the main thing that I would like to mention. I'm currently not taking my medication because I can't afford it. I work two jobs, and I have to choose between, am I going to pay my mortgage and provide for my children and try to keep their life stable and normal, or am I going to put us in the hole by having to pay this astronomical fee for a medication?

It has improved my cancer diagnosis, but I just can't put daily living expenses above a pill, even though it is a medication that I need. So, I'm very thankful that CMS is opening up this conversation and starting the negotiations and I'm hopeful that this will set a precedent for private insurance and other savings programs to assist patients. Once we get the negotiations underway, I'm prayerful that this will continue, that there will be negotiations with these pharmaceutical companies. I don't have a lot of options, and because it's metastatic, I will take medication until I die, or until it stops working. I would prefer to have the opportunity to take the medication and have it available as opposed to not taking it because I can't afford it. I think that my children deserve more than that. Thank you.

00:33:35

Moderator, PhD, RTI International

Thank you for your remarks. We do have a follow-up question. What other information or evidence do you think CMS should consider in the evaluation of Verzenio? And either one of you can answer, just raise your hand to be called on. **[Speaker 2]**, go ahead.

00:34:06

Speaker 2 (registered as a representative of a patient advocacy organization and patient)

Just consider the financial impact. Not only is it going to cut the cost for the government, but it also cuts the cost for the patients and all around. I love what was said earlier, if you don't consider the fact that if we can't afford the medicine, it's not going to work. We need to make this affordable and accessible to all.

00:34:41

Moderator, PhD, RTI International

And we have a little bit of time, **[Speaker 1]**, if you'd like to also answer?

00:34:46

Speaker 1 (registered as a representative of a patient advocacy organization)

Thank you. The concerns that are raised regarding the cost of the therapy are, to say they're legitimate, I think, minimizes the impact. The concern the National Minority Quality Forum has is that the evidence to support Verzenio, or any of these therapies, whether they are oncologics or others, is not based upon science that is inclusive of all the population cohorts who are affected by them. My response for the short term would be to continue to identify ways to make existing therapies more affordable for all population cohorts, but to do it in such a way that it does not compromise the research and innovation and the greater inclusion of populations who have historically been disenfranchised by the manner in which research is conducted. I think it requires a systemic revaluating, restructuring of the policies that govern the manner in which all therapies are developed in the United States. Thank you.

Speaker Remarks for Erleada

00:36:30

Moderator, PhD, RTI International

Thank you. Thank you both for your remarks today. We'll move on now to Erleada with one speaker. Erleada is commonly used to treat metastatic prostate cancer and non-metastatic prostate cancer.

The first speaker is **[Speaker 1]**. This speaker has indicated that there is no conflict of interest.

00:37:01

Speaker 1 (registered as a health care professional, representative of a patient advocacy organization, and caregiver)

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Hi, my name is **[Speaker 1]**. I'm a nurse practitioner working at a Federally Qualified Health Center as well as a patient and family advocate. I'm also the **[Redacted]** of Blackout PCa (Prostate Cancer), a 501(c)(3) nonprofit organization out of Pittsburgh, Pennsylvania, dedicated to prostate cancer awareness, screening, and education. I would like to note that the views I share today are my own and do not represent any organization or the government.



I'm here to urge Medicare to ensure and expand coverage for Erleada, a critical treatment option for individuals living with prostate cancer. This issue is deeply personal to me, not only as a clinician, but as a caregiver. My father passed away from metastatic prostate cancer in 2024. I walked alongside him through every stage of his illness. I witnessed the physical pain, the emotional toll, and the uncertainty that came with not knowing what options would be available next. As his disease progressed, our options became more and more limited. We reached a point where one of the only treatment options available to him was Pluvicto. While we were grateful for that option, it came late in his journey when the cancer had already taken so much from him. No family should have to wait until things get that far to have access to a meaningful treatment.

That experience changed me. It is why I speak up today. Patients and families deserve options earlier when there is still time, I believe the other panelists mentioned that, when there's still time to preserve quality of life, create memories, and hold on to hope.

Erleada represents more than just a medication. It represents time. Time for patients to live more fully. Time for families to be together. Time that cannot be replaced once it's gone.

The decisions being made through this current negotiation process are not abstract. They directly affect real people. They determine whether someone has access to a treatment that can give them more time, or whether they are left waiting until their condition worsens, and options become scarce, as my father experienced. Prostate cancer disproportionately affects older men, many of whom rely on Medicare. Without adequate coverage, treatments like Erleada may be out of reach for those who need the most.

In my role at a Federally Qualified Health Center, I care for patients who already face significant barriers. I see the stress and fear that comes with not being able to afford care. Costs should never be the reason someone cannot access a treatment that can make a meaningful difference in their life.

This is also about equity. Medicare beneficiaries deserve the same access to care and treatment options as anyone else. The current negotiation process may also have unintended consequences related to pharmaceutical innovations and the development of new therapies across all disease areas. It is important that the efforts to improve affordability do not inadvertently limit future treatment options for patients.

I respectfully urge Medicare to continue modernizing its policies to ensure access to treatments like Erleada so that patients have options earlier, families have more time, and fewer people have to experience what my father and our family went through. Thank you for your time and consideration.

00:41:43

Moderator, PhD, RTI International

Thank you for your remarks. I do have one follow-up question for you. In your experience, what considerations drive treatment selection among Erleada and its potential therapeutic alternatives for its indications?

00:42:02

Speaker 1 (registered as a health care professional, representative of a patient advocacy organization, and caregiver)

I believe I'll go back to what I mentioned as far as affordability and access to that medication. It needs to be affordable. Like I mentioned, I work at a Federally Qualified Health Center, it needs to

be able to be accessed for all patients. All patients. Like I mentioned, Medicare patients are older. They need to be able to afford it. That's pretty much the gist of it. I don't want to go too much further. I can keep going and on and on, but I believe that affordability and access is important.

Speaker Remarks for Lenvima

00:43:00

Moderator, PhD, RTI International

Okay, thank you for your remarks. We will move on now to Lenvima with one speaker. Lenvima is commonly used to treat endometrial cancer, kidney cancer, liver cancer, and thyroid cancer.

The speaker is [Speaker 1]. This speaker has indicated that there is no conflict of interest.

00:43:57

Speaker 1 (registered as a representative of a patient advocacy organization)

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Thank you for the opportunity to speak today. I'm representing the Community Liver Alliance, the leading national nonprofit organization in the liver space. We're driving measurable impact through education, advocacy, research, and community-based solutions, and I want to center my remarks on what matters most to people living with liver cancer, which is having access to appropriate treatment options at every stage of their disease.

For many years, patients with hepatocellular carcinoma, or HCC, had very limited therapies that meaningfully improved outcomes. And today, we've made progress, but that progress depends on maintaining access to a range of treatments. Liver cancer is not a one-size-fits-all disease. It is clinically complex, and most patients are also managing underlying liver disease, and because of this, no single therapy is appropriate for every patient and treatment decision must be individualized. And most importantly, these decisions are guided by well-established clinical practice guidelines, such as those from the American Association for the Study of Liver Diseases and the National Comprehensive Cancer Network, which both emphasize individualized treatment selection based on disease stage, liver function, prior therapies, and patient characteristics. These guidelines support the use of multiple therapeutic options rather than a single, fixed pathway. And

as the disease progresses, patients often move through multiple lines of therapy. Cancer can recur, or patients may no longer tolerate a given treatment, and when that happens, having other options available is critical.

This is where the concept of sequencing becomes important. In simple terms, sequencing means starting with one therapy, monitoring response, and then transitioning to another therapy, if needed. It's not a single decision; it's a continuum of care. And increasingly, in some settings, clinicians may also consider combination approaches, depending on the patient and the clinical context. So, preserving access to multiple therapies is not redundancy, it is essential to delivering appropriate care over time.

Turning specifically to lenvatinib, which plays an important role in this treatment landscape, one of its key distinctions is that it's an oral therapy, which is clinically meaningful for many patients. Compared to infusion-based treatments, oral therapy can reduce the need for frequent clinic visits, minimize the travel burden, decrease time spent in medical settings, and allow patients to remain more engaged in daily life and caregiving responsibilities. These factors are especially important for older adults, patients experiencing fatigue, and those who may face transportation or mobility challenges.

In addition, lenvatinib has a well-established safety profile, and clinicians have experienced managing its side effects. That predictability supports better patient counseling and more confident treatment decisions. It's also worth noting that this therapy has been used across multiple cancer types, including thyroid, endometrial, and renal cancers. This broader clinical experience provides a stronger foundation of real-world evidence and provider familiarity, which is meaningful from both a clinical and a policy perspective.

And at the same time, we want to emphasize that coverage and access policies directly influence whether patients can benefit from these therapies. There are barriers such as prior authorization, cost sharing, and formulary restrictions, and those can delay treatment or interrupt care. In a progressive cancer like HCC, those delays can seriously lead to consequences.

Finally, there are also improvements happening in liver cancer detection. Enhanced imaging, better surveillance strategies, and emerging tools are allowing for earlier diagnosis. As more patients are identified earlier, it becomes even more important that they have access to a full range of treatment options. Ensuring that appropriate screening and surveillance are covered by CMS is essential so patients can be identified earlier and connected to timely, appropriate treatment options.

In closing, liver cancer care requires flexibility, continuity, and access. Drug price negotiation efforts should support affordability but also preserve patient choice and timely access to clinically appropriate therapies, including oral options like lenvatinib, because for patients, access to options is not theoretical. It's what allows them to continue treatment and maintain quality of life. I thank you.

00:49:22

Moderator, PhD, RTI International

Thank you for your remarks. I have one follow-up question for you. Thinking about the topics we discussed today, how would you summarize the importance of Lenvima for people with this health condition?

00:49:37

Speaker 1 (registered as a representative of a patient advocacy organization)

I think that there are several benefits, but the biggest, and I just touched upon that, is this is an oral option, and this is really important because of all of the social determinants of health that intersect with patients living with liver cancer, whether it's childcare or travel, or they just simply don't feel well enough to travel, or to take on the infusion-based treatment. So, this really does free up, and it also is more cost-effective as well for patients and for the providers. We also feel that because it's a well-established therapy, and clinicians are familiar with it, and it also is used across multiple cancer types that its efficacy is broad and strong. And I hope that answers your question.

00:50:36

Moderator, PhD, RTI International

All right, thank you for your remarks.

Closing

00:50:41

Moderator, PhD, RTI International

That brings us to the end of this town hall session. I would like to thank all our speakers for joining us today and providing important input for the Medicare Drug Price Negotiation Program. You can find additional information and news about the Negotiation Program on the CMS website listed on this slide. If you have questions, please contact CMS using the email address listed on this slide. Thank you and enjoy the rest of your day.

===== END OF TRANSCRIPT =====

For a list of the drugs selected for the third cycle of the Medicare Drug Price Negotiation Program, click on the following link: <https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf>

For more information on the Medicare Drug Price Negotiation Program, please click on the following link: <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program>