National Government Services, INC

Moderator: Dr. Olatokunbo Awodele

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11:00 am

Dr. Olatokunbo Awodele: Good afternoon, everyone. Welcome to National Government Services J6JK Open Meeting being held today, June 25, 2025. My name is Dr. Olatokunbo Awodele, and I'll be facilitating today's meeting. We deeply appreciate your participation as we address several pivotal topics today. Please note that this meeting will proceed according to Eastern Time and is being recorded and transcribed for accuracy. If you wish to make a comment during our discussion at the appointed time, please raise your hand and (Alicia) or (Crystal) will help you unmute yourself, and I will call on you to share your thoughts.

Let's begin with our agenda and the accompanying PowerPoint slides. So, first slide shows all the contractor medical directors here at NGS, and I'd like to thank all of them for being present for this presentation, this open meeting. Next slide, please. So, the proposed LCDs that we're going to discuss today are shown on the slide. They

are the DRAFT-LCD-40168, which is titled Superficial Radiation Therapy for the Treatment of Non-Melanoma Skin Cancers.

The next one is the DRAFT-LCD-39314, which is titled Off-Label Use of Intravenous Immune Globulin. The next one is DRAFT-LCD-39297, which is titled Off-Label Use of Rituximab and Rituximab Biosimilars. And the last one is DRAFT-LCD-38367, which is titled, Fluid Jets System Treatment for Lower Urinary Tract Symptoms/Benign Prostatic Hypertrophy. Next slide, please.

So, we're going to start off with the DRAFT-LCD-40168, superficial radiation therapy for the treatment of non-melanoma skin cancers. We have several presenters lined up for today, and I will first of all go into a brief synopsis of what the Draft LCD entails. So, this is a local coverage determination which has been developed to create a policy consistent with current evidence for the treatment of non-melanoma skin cancers with superficial radiation therapy, and address a variant of superficial radiation therapy utilizing high-resolution ultrasound, also known as HRUS, guidance, and electronic brachytherapy, which is also EBT, for the treatment of non-melanoma skin

cancers. This LCD outlines limited coverage for SRT, with specific details under coverage indications, limitations, and/or medical necessity. Next slide, please.

So, covered indications. Under indications of coverage, the medical documentation must support the medical necessity for the use of superficial radiation therapy as the primary modality of treatment of the non-melanoma skin cancer. If the beneficiary meets all the criteria as outlined in the LCD, the use of SRT is considered reasonable and necessary for the following conditions.

The first one would be the presence of low-risk cutaneous basal cell carcinoma, or high-risk basal cell carcinoma as per the NCCN, ASTRO, and AAD guidelines, with documentation that the patient is a non-surgical candidate or, number two, the presence of a low-risk cutaneous squamous cell carcinoma, or high-risk squamous cell carcinoma as per NCCN, ASTRO, and AAD guidelines, with documentation that the patient is a non-surgical candidate, or the presence of a cutaneous squamous cell carcinoma in situ as per NCCN, ASTRO, and AAD guidelines, with documentation, once again, that the patient is a non-surgical candidate. Next slide, please.

So, limitations. Number one, the use of high-resolution ultrasound to guide superficial radiation therapy delivery and to assess lesion reduction during the superficial radiation treatment protocol is not supported by literature, and thus not considered reasonable and necessary. Number two, based upon the consensus of the literature and the recommendations of the AAD, ASTRO, and ADS, the use of electronic surface brachytherapy, also known as EBT, for the treatment of non-melanoma squamous cancers, is not considered reasonable and necessary at this time. Next slide, please.

So, the following are considered not reasonable and necessary. Number one, first-line treatment options in surgical candidates. Next is the use of SRT for the treatment of advanced BCC and SCC. Next is the use of SRT for the treatment of patients with non-melanoma skin cancers who have contraindications to radiation therapy. Next is cutaneous tumors arising in previously irradiated fields, or where overlapping fields would be expected.

Next is cutaneous squamous cell carcinomas with size

greater than 4 centimeters, cutaneous basal cell carcinomas with size greater than 4 centimeters, cutaneous non-melanoma skin cancers with depth greater than six millimeters, cutaneous non-melanoma skin cancers with aggressive morphology, cutaneous tumors with perineural or perivascular invasion as sole treatment option, and very high-risk squamous cell carcinomas. Next slide, please.

So, we're going to now move on to the portion where we will hear from our registered commenters on this Draft LCD. First up is Dr. Glenn Goldman, who is with the American College of Mohs Surgery. So, we know Dr. Goldman is here. Dr. Goldman, could you raise your hand so that you can be unmuted? Okay. All right, I'm going to hand over to Dr. Goldman. Can you please unmute yourself, sir?

Dr. Glenn Goldman: Am I back?

Dr. Olatokunbo Awodele: Yes, sir. We can hear you. Thank you.

Dr. Glenn Goldman: Okay. Thank you very much for the opportunity to speak with you today. The ACMS supports the proposed

LCD as written. The proposed LCD provides reasonable safeguards for patients and is similar to current LCDs for Mohs micrographic surgery. LCDs, as you know, are needed to safeguard the integrity of the Medicare program, and to protect beneficiaries from unproven and medically unnecessary services. Next slide.

My name is Glenn Goldman. I'm Emeritus Professor and former Chief of Dermatology. I've been involved in education for 30 years, and I'm a frequent reviewer for the AAD, JAMA Derm, Derm Surgery, and other publications. I have 56 publications of my own, mostly peer-reviewed, and I've trained about 100 individuals. Next slide.

I am here today to support what's right for our patients, to support the scientifically valid LCD process, and to support our local MAC in appropriate decisions when there is likely pressure from outside influences to go against the science. I am here to protect the Medicare trust fund and to counter lobbying efforts by private equity to promote an unproven therapy for financial gain, along with physicians who have chosen to put income over patient care. Next slide.

As you see from a recent publication in the Journal of the American Academy of Dermatology, there has been an explosion in the use of image-guided superficial radiation therapy. The JAAD is our flagship peer-reviewed journal. Slide. These are the codes that are being used for SRT and ancillary services. Next slide.

If you look in this table from the JAAD article, in the last number where you see RT ultrasound guidance, you will note a 233% increase in use of this code at a time when approximately 10% increase in skin cancer was noted. We estimate that in 2023, IGSRT cost the Medicare Trust Fund approximately $170 million to treat 16,000 skin cancers at a cost of over $10,000 per lesion. Individual physicians have collected up to $3.6 million per year providing this treatment to Medicare patients. Next slide.

The proposed LCD is based on a comprehensive literature review and demonstrates that SRT is not first-line therapy and that image-guided SRT is not proven to offer any advantage over SRT. You will hear from those who oppose the LCD that this will restrict access to radiation therapy. This is untrue. The LCD does not restrict access to

SRT when it is clinically indicated. What it does is to restrict billing for an unproven imaging technology. Next slide.

NCC guidelines support the treatment of non-melanoma skin cancer when the patient is a non-surgical treatment candidate using SRT. Of all standard treatments, radiation is by far the most expensive. We believe strongly that the reason we are seeing this very expensive treatment utilized frequently is due to financial gain for those involved. Next slide. You may move on. Next slide.

The proposed LCD states that the use of high-resolution ultrasound to guide SRT and to assess lesion reduction during superficial radiation treatment is not considered reasonable and necessary and is not supported by the literature. The ACMS agrees with this statement and believes that the LCD is sound. Next slide.

IGSRT proponents cite several articles to claim that IGSRT is superior to SRT, that it is superior to surgery, and that it should be first-line therapy. A critical appraisal of literature demonstrates that none of these claims are supported. Next slide. The studies supporting IGSRT are

abysmal. They are non-randomized, non-controlled, unblinded, retrospective studies. They are published universally in pay-to-play journals. Most notably, tremendous numbers of patients and tumors are lost to follow-up. Next slide.

These studies have no blinded central review, no control groups, no randomization, and weak to non-existing peer review. The authors are highly conflicted and usually have financial interests in IGSRT. None of these studies would have been published in a peer-reviewed journal. Next slide.

In the attached article, which is frequently cited by those who perform IGSRT, the authors state that they have cure rates similar to and potentially superior to traditional SRT and surgical options. However, in yellow, at one year, 45% of lesions were lost to follow-up. From a scientific perspective, no claim of a cure can be based on a follow-up of 55%. Next slide.

Similarly, in a study of 20,000 lesions used to quote a 99.5% cure rate, the loss to follow-up at two years is 60%, and at six years, the loss to follow-up is 98%. I feel that it is

preposterous to claim a cure rate based on such poor follow-up. Next slide. A study claiming that high-resolution ultrasound at each treatment guides therapy and is necessary. No evidence, however, was presented to demonstrate that daily alterations reflected tumor changes. In fact, this probably just represents edema, something that is uniformly seen with radiation therapy. There is no validated tool or study that proves ultrasound findings correspond to histologic findings in non-melanoma skin cancer. Next slide.

There is no evidence presented that the daily alterations reflect tumor changes. There is no validated tool or study that proves that ultrasound findings correspond directly with histologic findings in non-melanoma skin cancers. Next slide. There simply are no good studies showing SRT versus image-guided SRT. There is simply a claim that this is necessary. In fact, skin cancers that are amenable to SRT are superficial without extensive dermal involvement, and they can simply be marked with a 10 and treated accordingly. Next slide.

IGSRT is experimental. Those tumors that are amenable to treatment with SRT simply do not need image

guidance. Skin cancers simply do not grow or change day-to-day, and quote, adaptive therapy, as it is called, is simply a neologism to explain the need to bill excessively for an unnecessary service.

Just this month, in the Journal of the American Academy of Dermatology, Dr. Hao Feng, and colleagues at the University of Connecticut, reported that image guidance contributes substantial cost and rarely informs dosimetry management in superficial radiation. Specifically, the authors note that dosing changes were exceptionally minor, and they were associated with very high costs. Next slide. Next slide.

Despite the lack of evidence, ultrasound guidance use has exploded. This is not a medically necessary procedure. The codes that are being used and coded are codes that were designed for the treatment of internal malignancies using substantial imaging devices for lesions like prostate cancer and lung cancer where objects and organs literally can shift in location requiring treatment. Next.

As for provider qualifications, the LCD promotes

reasonable training requirements for those providing SRT. The ACMS supports these requirements. Of note, most LCDs also have training requirements, so this is consistent. Next. We agree with the LCD proposed exclusion for treatment of electronic brachytherapy. Next.

Missing in the discussions by proponents of IGSRT is the mutagenic potential for radiation. Early in my career, I treated many individuals with hundreds of disfiguring tumors caused by radiation for acne vulgaris. We are now seeing young people treated with IGSRT. This is exceptionally concerning. Next slide.

This LCD will help Medicare, it will help patients, and it will help the conscientious provider. The LCD does not restrict the use of superficial radiation therapy when clinically indicated. It does recognize there is no good evidence for the very expensive image guidance and high-resolution ultrasound. Next slide.

I wish to state for the record that providers are using this modality because it is non-surgical, it is easy, and it is lucrative. They claim that the procedure causes no scar, no wound, and almost never has recurrences. I am a

dermatologic surgeon. What I do causes a scar, sometimes fails, it's messy, and it's hard.

I have seen horrible porcelain white SRT scars, severe recurrences, and non-healing ulcerations from SRT, including in a relative. No treatment is so wonderful as claimed by those promoting IGSRT. My mom taught me early in life that if something is too good to be true, it probably is not. Next slide.

I am so pleased with the decisions made by the MAC that they are based on science and not lobbying. If I felt this treatment worked, I would happily add this to my practice. It's easier than what I do, and it pays much more. But I am here on the side of the patient and to protect the Medicare Trust Fund.

Sadly, right now, I feel a little bit like David in the photo. We cannot compete against the flood of slick advertising and the lobbying of our senior officials. I leave you with the fact that this treatment is unproven. We are grateful for the time we have had to speak with you today, and we thank you so much for your scientific and literature approach to this subject. I appreciate this time. Thank

you.

Dr. Olatokunbo Awodele: Thank you very much, Dr. Goldman. And we request that you please send your comments in writing along with any literature that you cited that you feel will help support your position. So, thank you very much, Dr. Goldman. Next, we're going to have Dr. Jonathan Chang and Robert Burnside from Genesis Cancer Center and Elekta, Inc. Both gentlemen, could you please - whoever is speaking first, please unmute - raise your hand?

Dr. Jonathan Chang: Yes, can you hear me? This is Dr. Jonathan Chang.

Dr. Olatokunbo Awodele: This is Dr. Chang?

Dr. Jonathan Chang: Yes.

Dr. Olatokunbo Awodele: Yes, I can hear you, so you may proceed.

Dr. Jonathan Chang: Perfect. Well, good morning. My name is Dr. Jonathan Chang. I'm a board-certified radiation oncologist at Genesis Cancer Center in Houston, Texas. And I'm joined here by Mr. Rob Burnside from Elekta. Today, I'm here to speak not on behalf of the industry, but

as a treating physician for over thousands of Medicare patients, many of whom rely on electronic brachytherapy, which we'll be calling EBT going forward, as a very safe and effective treatment option for non-melanoma skin cancers. Next slide.

So, what's at stake here? Well, if the proposed LCD is adopted and the EBT coverage is removed, thousands of Medicare beneficiaries, many of which are elderly, frail, or medically inoperable, will be denied access to a curative, non-invasive, and highly effective treatment. EBT has been shown to achieve high control rates above 98%, with minimal toxicity, favorable cosmesis, and short treatment durations. This is not an experimental medicine. This is evidence-based care, already utilized across the country for over a decade. Next slide, please.

So, what is the current concern with the draft?
Well, the draft LCD failed to consider over 10 plus years of published literature, peer-reviewed literature on high dose rate EBT. It relies heavily on a 2019 consensus guideline that was created before a long-term EBT outcome data was even available. Worse yet, that guideline included no EBT-using physicians, and was

developed by individuals affiliated with a competing technology vendor, thereby representing a significant conflict of interest. There are well over 14 peer-reviewed publications that have documented EBT's safety and efficacy, none of which were reviewed or acknowledged in the current LCD. Next slide.

So, let me be clear. EBT is actually aligned with all major national guidelines such as NCCN, ASTRO, and AAD. They have all endorsed superficial radiation therapy for non-melanoma skin cancer patients and non-surgical candidates. EBT is just a modern standardized variation of superficial radiation therapy.

Compared to SRT, which is superficial radiation therapy, EBT often uses fewer fractions, have more consistent dosimetry, and better tolerated in frail patients. Unfortunately, there are no randomized studies proving that SRT is superior because such trials would be considered unethical in elderly cancer patients. However, retrospective and matched cohort studies such as Patel 2017 and the long-term study from Doggett 2023, have shown that EBT compared favorably with SRT and even no surgery in selected cases. Next slide.

So, the American Medical Association held two CPT editorial panel meetings, one in September 2024, and one in 2025. Along with ASTRO, they have reviewed the clinical data and made its judgment. In May 2025, AMA voted not to separate SRT and EBT into different codes. Instead, it created a separate code with the CPT code 77X07, which will be effective January of 2026, and this will be encompassing both modalities.

This actually affirms that clinical equivalency acknowledge that both are reasonable and necessary in appropriate patients. And they both use very similar photon energies, and they treat the same anatomic and pathologic indication. The leading EBT coverage now would contradict the national coding alignment and the judgment of leading specialty societies. Next slide.

So, here are the differences between high-dose rate EBT versus SRT. First, as you can see on the left, EBT uses much less fractionation. We call that hyperfractionation. And we use anywhere between eight to 12 treatments, which help enhance patient compliance and lower patient costs. Versus that of SRT, they're generally in the 20 to 30

fraction range, which can obviously have negative impact on patient compliance and increasing patient costs, as mentioned earlier in the previous speaker.

Secondly, EBT requires specialized training staffing, such as ARRT-certified radiation therapists, who are always involved and remain in the room during treatment, versus that of SRT, they're often provided by medical assistants and not necessarily the ARRT-certified radiation therapists, and they are generally required in the outside of the room and not monitoring on a close-up basis.

Third, EBT is always supported by board-certified radiation oncologists and medical physicists to ensure that we're delivering accurate and safe delivery of these high-radiation doses. The doses that we generally prescribe are 400 centigrade or higher, up to 500 centigrade or more. Whereas in SRT, someone like myself, radiation oncologists, are almost never involved in the instrument process, and it's due to lower daily dose that they're prescribing, generally 200 to 300 centigrade per fraction. Lastly, EBT has stricter State and federal regulatory oversight than that of SRT. It's often constantly under high-dose brachytherapy because the

rules are much stricter for EBT versus that of SRT. Next slide.

So, here's our ask. We respectfully request that the Section 5 of the draft LCD, which proposes to limit EBT coverage, be removed. This is not just a treatment modality. This is about preserving patient access, honoring guideline-based care, and protecting patient autonomy. Denying EBT disregards both the science and the human impact on elderly patients with limited options, especially those non-surgical elderly patients with skin cancer. Next slide.

This is just a short list of the bibliography and many evidence that's currently available. For instance, the first study here from Doggett, et al., was a long-term study that showed a 1.1% recurrence rate at 7.5 years, and that was the longest EBT follow-up up to date. This study was not considered in the consensus guideline.

We have Patel, et al., in 2017, which was a matched-pair cohort study looking at 369 patients comparing EBT versus Mohs surgery. And this one showed no significant difference in terms of recurrence or cosmesis in 3.4 years

follow-up. And you've got studies from (unintelligible) in 2015, Goyal 2021, Cheung 2022, and myself Chang 2024, have all shown 95% to 98% control rates with excellent cosmetic results. These data span thousands of regions across multiple continents, devices, and patient populations, including many, many Medicare Beneficiaries. Next slide, please.

So, in closing, in summary, high-dose rate EBT is clinically effective. It's been proven through multiple peer-reviewed journals and articles and thousands of patients. It's endorsed in national coding and by many national societies. It's aligned with the guidelines, national guidelines and the societies that I've mentioned earlier. It's critically important for elderly patients. We therefore ask you to maintain the coverage for EBT under the same standard applied to SRT. And thank you again for your time and consideration. I welcome any questions.

Dr. Olatokunbo Awodele: Well, thank you, Dr. Chang, for your presentation. And as I said to Dr. Goldman, if you could, if you haven't already, please submit your comments that you've presented here today in writing, along with the referenced literature, and we would really appreciate

that. So, we're going to move on to Dr. Yu. I see that Dr. Yu raised his hand. And Dr. Yu, could you try speaking so we can see if we can hear you. We can't hear you. If you can unmute yourself. Dr. Yu? Can you try unmuting yourself, sir? We still can't hear you.

All right. Maybe while we're working on that, we can go on to Dr. Farberg. Dr. Farberg, could you try speaking?

Operator: I have allowed Dr. Farberg's mic. Just needs to unmute.

Dr. Olatokunbo Awodele: Dr. Farberg, can you please try unmuting yourself? Sometimes people are double-muted, so you might have to - so, Dr. Yu, also - Dr. Yu, could you try speaking again? Okay, let's try Dr. Hopkins, if he's on. Dr. Hopkins, could you raise your hand if you're on?

Operator: I don't believe Dr. Hopkins is on at this time.

Dr. Olatokunbo Awodele: Okay. So, Dr. Yu's hand went down now. Dr. Yu, could you try raising your hand again? Okay, it's up. And unmuting yourself. So, if you - Dr. Farberg, Dr. Yu, if you could just hover on your name, you'll see that the microphone, it's currently showing that you're muted. If

you can just click on that to unmute yourself. Okay. Dr. Todd has his hand up. Dr. Todd, I don't have you as a registered speaker. Seems like Dr. Yu went out. Maybe he's trying to go back - go out and come back in. Dr. Farberg, do you want to try that as well? Okay, is Dr. Hopkins on by any chance?

Operator: Not that I'm seeing.

Dr. Olatokunbo Awodele: Okay. Dr. Yu just came back and he is unmuted. So, if we can - he has his hand raised. Oh, somebody just - Dr. Yu, what did you do? You were unmuted before.

Dr. Lio Yu: Hi, can you hear me?

Dr. Olatokunbo Awodele: Yes, we can. Awesome.

Dr. Lio Yu: Oh, fantastic. I had to log out and log back in. So, I wasn't ...

Dr. Olatokunbo Awodele: Thank you for doing that. We appreciate that.

Dr. Lio Yu: So, can you go back to the beginning of the presentation?

Dr. Olatokunbo Awodele: Yes, so the floor is yours, sir.

Dr. Lio Yu: I'm sorry about that. All right, can I begin?

Dr. Olatokunbo Awodele: Yes, you may begin.

Dr. Lio Yu: Okay, thank you, and thank you for the opportunity to speak today. My name is Dr. Lio Yu. I'm a board-certified radiation oncologist, and I've been practicing over 30 years. I'm also the chair of research for Dermatology Association of Radiation Therapy, and the lead author on several of the largest contemporary studies on IGSRT. Next slide, please.

Just to briefly introduce myself, context, I trained at Yale in molecular biophysics and biochemistry, followed by radiation oncology training at major institutions, including Mount Sinai, Memorial Sloan-Kettering, Dana-Farber, and Montefiore. I currently serve as clinical director of radiation oncology and the chair of research at DART.

I've authored or co-authored multiple peer-reviewed studies and book chapters focused on head and neck cancers, skin cancer, and radiation protocols. In recent years, I've led some of the largest IGSRT outcome studies in the United States, with over 20,000 lesions analyzed, many of which are directly relevant to the policy we're discussing today. I also serve as a consultant to industry partners and believe strongly in transparent data-driven decision-making. Next slide, please.

So, today I want to talk to you not just as a researcher, but as someone who treats patients every week with this technology. I've seen firsthand how image-guided superficial radiation therapy, IGSRT, is changing lives. But unfortunately, the current draft LCD doesn't reflect that reality. This policy overlooks a large body of new data and seems to conflate old SRT methods with the modern IGSRT, which uses daily ultrasound guidance. That distinction is crucial. It's the difference between guessing and knowing, between static treatments and real-time response. Next slide, please.

So, here's the clinical bottom line. We have multiple studies with freedom from recurrence rates of over 99%,

and these studies also demonstrate that there was no difference by various different factors, risk factors, patient factors. For instance, basal cells and squamous cell carcinoma both had greater than 99% plus control rate.

There was no difference by patient age, by tumor location, whether the head and neck or not head and neck, by patient sex, and by stage. There is a slightly increased cure rate for lower stage, understandably, but still it's greater than 99% at two, four, and six years. There was no difference by co-mobility or socioeconomic status Next slide, please.

Across 15 peer-reviewed studies, IGSRT consistently achieved long-term local control rates above 99% at two, four, and even six years of follow-up. And this isn't cherry-picked data from one institution. These are large, multi-center studies using real-world patient populations. And contrary to what the previous Mohs surgeon said, the studies are well-run and there aren't a lot to follow, but I will address that a little later on. In our large IGSRT studies, which I've personally authored or reviewed several of them, we tracked these 20,000 cases, and the local control rate exceeded 99% in pretty much all of the

patient populations. And that's not a fluke. Next slide, please.

So, what do they all have in common? They use the LAD-Yu protocol, meaning image-guided superficial radiation therapy with daily high-resolution thermal ultrasound. IGSRT is not just a minor tweak on an old SRT machine. It's an entirely new class of technology. We paired this ultrasound with precise image-guided radiation delivery. That capability simply wasn't existent before 2016.

It's like comparing a flip phone to a smartphone. Sure, both make calls, but one is clearly smarter, faster, and safer. So, to lump IGSRT with legacy SRT approaches, ignores the core innovation that makes these results possible, daily ultrasound-based guidance and real-time treatment adaptation. Every one of these studies show that when imaging is added, outcomes improve significantly, and that's not a coincidence. It's a reproducible clinical effect, and the meta-analyses and regression studies confirm it. Next slide.

Now, traditional SRT plateaued with cure rates about 90% to 95% range, that's good. But we're consistently

seeing over 99% recurrence-free survival with IGSRT. And why is that? That's because of daily imaging. Nearly every lesion undergoes anatomic changes during treatment, changes in depth, width, and density, as opposed to what the surgeon said, who's really, I feel ignorant about this technology.

We actually see the tumor very, very well. It's not like an abdominal ultrasound where you can't make heads or tails. You can see the tumor very clearly, and we can also see edema as well. So, without daily ultrasound, these changes are invisible. With IGSRT, we see them in real time and adjust accordingly. That's why these cure rates are not just better, they're statistically superior. Next slide.

So, this was especially troubling. Even ECRI, the same organization CMS often turns to for technology evaluations, issued a favorable score for IGSRT. This wasn't an industry-paid review. It was independent, evidence-based, and recognized both the effectiveness and safety of the technology. Yet the LCD doesn't even mention it. So, if CMS's own preferred evaluator says IGSRT deserves a favorable rating, that should be central to the policy discussion, not excluded from it. Next slide.

So, this is not just a niche technology for a narrow group. We have strong data on basal cell, including aggressive subtypes, squamous cell carcinoma and squamous cell carcinoma in situ. Across the board, we're seeing greater than 99% local control. And that's in studies with large sample sizes, real-world complexity, and six years of follow-up, without loss of follow-up. Next slide, please.

So, with regard to the conclusions about the imaging, this is where the evidence becomes overwhelming. Whether it's traditional SRT, external beam radiation therapy, or even older brachytherapy, adding high-resolution dermal ultrasound improves the outcome, and that's not a guess. It's been proven through meta-analyses, logistic regression and comparisons, poor cohort studies, and this is what makes IGSRT a separate class, not just radiations. It's intelligent, adaptive, and image-guided therapy. And that image guidance explains the performance difference. Next slide, please.

So, in conclusion, and this is not, by the way, the last slide. I have more to go on. It's not an experimental tool. It's a first-line treatment for early-stage, non-melanoma skin

cancer in patients who are not good surgical candidates. It's safe, it's non-invasive, it's supported by strong long-term data. So, since 2016, there's been over 120,000 patients that have been treated with IGSRT. And it's available in hundreds of clinics across the country.

For patients who are elderly, on blood thinners, in poor condition, or otherwise not candidate for Mohs, this is the most effective non-surgical option we have. And in many communities, it's already become the standard of care. And why is that? Because it works, especially in patients that Medicare is supposed to protect the most, the elderly, the frail, and the medically complex.

If it didn't work over the past several years, I don't think patients would be flocking to it and even most surgeons. In fact, I think almost half the population of patients are in most surgery clinics because these patients, they want the same control rate without having to undergo surgery, unnecessary surgery, in my opinion. Next slide. Next slide.

So, we contribute - can you go back one slide? Go back one, please. Yes, so my colleagues and I have published peer-reviewed - let's go to the bibliography slide. We

published peer-reviewed studies in journals that are well-respected, such as in Advances in Radiation Oncology, BMT Cancer, Journal of Pathology, and Journal of Cancer Research in Clinical Oncology. These are not just, you know, poor journals. They're rigorously reviewed, peer-reviewed, and has undergone significant scrutiny. Next slide, please. Go to the next slide, please.

Here's a case on a patient with a high-risk basal cell carcinoma. It's a micronodular, and we see the before and after photos. So, this shows that the patient doesn't have to undergo surgery and doesn't have to have a scar or even a reconstruction. You know, this is a great option. That's why patients flock to it. Next slide, please.

Now, I want to draw your attention to a particularly damaging issue, the mischaracterization of IGSRT by some groups like the American College of Mohs Surgery. The doctor, what he said on his presentation is flat out wrong, okay? This is like the pot calling the kettle black. The surgeons have the financial incentive to keep doing unnecessary surgeries, in my opinion, okay?

And we've shown that IGSRT has comparable and

sometimes even better cure rates than Mohs surgery. And they're using basically smoke and mirrors and distortion, misinformation, disinformation, to try to show this. Here is a handout that the American College of Mohs Surgery gave to their providers. And it deliberately conflates old legacy SRT with IGSRT. It's showing that SRT has a failure rate of up to 16% compared to Mohs, which is up to 2.5%. But in fact, IGSRT, the local control rate is less than 1% - I mean, local failure rate is less than 1%. Next slide.

In their bibliography, they stuck in the references for IGSRT, but they still cite the lower control rate. Next slide. So, I just want to address the question validity of data suggesting thousands of cases, 20,000 patients' studies were lost, quote, lost to follow-up. This critique reflects a basic misunderstanding of clinical statistics, particularly Kaplan-Meier analysis.

These studies didn't just ignore patients who dropped out or were unavailable. They used standard time to invent methods that account for variable follow-up durations and censor each patient individually based on the actual follow-up data available. In fact, all our large IGSRT studies applied Kaplan-Meier methodology

correctly, and many also incorporated competing risk models to account for deaths unrelated to skin cancer. Next slide.

Dr. Olatokunbo Awodele: Dr. Yu.

Dr. Lio Yu: Yes.

Dr. Olatokunbo Awodele: I just wanted to indicate that you're slightly over time, but if you could please just bear that in mind and try and wrap up.

Dr. Lio Yu: Oh, sure. I'll finish up within the next minute. Next slide, please.

Dr. Olatokunbo Awodele: And afterwards, I would like you to talk about your conflict of interest as well because there wasn't a slide in the beginning stating that, so thank you.

Dr. Lio Yu: Yes, I had that at the beginning, at the bottom of - so there was also talk about a few percentage differences in the LCD. So, does 1% or 2% matter? Well, yes, if you have 1% in 5 million cases, and that's as of 2012, that's 50,000 cases. If you have 2%, that's 100,000 cases. So, if you have

a better cure rate for just 2%, and we know the percentage is actually much higher, that's 100,000 lesions that may require salvage therapy and it's very expensive. And this is something that CMS needs to look at. Next slide. Next slide. Next slide. I'm going to skip over these. Next slide. Next slide.

Okay, so in previous slides, I showed a comparative study I did using meta-analyses and logistic regression analysis that shows that IGSRT, which is shown here in red, okay, is statistically superior to non-image-guided modalities, which is in black. Okay, that's pretty clear. So, I want to conclude at this time that IGSRT is not an emerging technology. It's not experimental. It's established. It's safe, precise, and supported by a deep and growing body of peer-reviewed clinical data.

We have a reproducible protocol, multi-year outcomes, independent validation by ECRI, consistent success across subtypes and patient demographics, and to group it with outdated radiation techniques is to misinterpret the science, but to do so in a way that affects real patients and the patients that really need access to care the most. It's time for the policy to catch up with the evidence, and I

urge this body to rewrite the LCD in consultation with clinicians, researchers, and the most current data available. Thank you.

Dr. Olatokunbo Awodele: Thank you, sir. So, before you sign off, if we can go back to his first slide, please, and if you can just state the conflict of interest just for recording so that we can have it on record.

Dr. Lio Yu: Yes, I think it's the second slide. Here we go.

Dr. Olatokunbo Awodele: Second slide. Okay.

Dr. Lio Yu: If you look at the bottom, I'm a consultant to SkinCure Oncology and previously a consultant to Bayer Pharmaceuticals. But again, this is all data-driven. And in fact, it's the opposite. I care about patients. I care about patients wanting to get treatments without unnecessary surgery, and that's why I'm doing it. Thank you.

Dr. Olatokunbo Awodele: Thank you very much, sir, and we appreciate that. If you could please send the comments in writing, if you haven't already, with the supporting literature that you also spoke about so eloquently in your

presentation, we would appreciate that. So, thank you very much for making time for us this afternoon. And so, we're going to move on to Dr. Aaron Farberg from Bayer Dermatology. Dr. Farberg, I saw you unmuted before, so if you could try unmuting yourself, please. Okay. No. Could we try unmuting him? Have we unmuted him?

Operator: His mic is. enabled.

Dr. Olatokunbo Awodele: It's enabled? Okay.

Operator: So, he should be able to self-unmute.

Dr. Olatokunbo Awodele: So, sir, could you please try self-unmuting? I thought I saw him unmuted during the - okay, it looks like he has signed off again, so he can come back in. Dr. Janine Hopkins, are you on the call? I don't see Dr. Hopkins, unless she's on my - Dr. Hopkins, if you're on the call, could you identify yourself by raising your hand, please? Okay, I believe Dr. Farberg is trying to come back in. Okay, Dr. Farberg is back in. We enabled his mic, I presume. Dr. Farberg, can you try unmuting, please? (Alicia), is there a way to move Dr. Farberg to presenters and see whether that will help the situation?

Dr. Aaron Farberg: Hello. Is this working?

Dr. Olatokunbo Awodele: Hi. We can hear you, yes.

Dr. Aaron Farberg: Oh, wow.

Dr. Olatokunbo Awodele: All right.

Dr. Aaron Farberg: I feel like I'm free at last.

Dr. Olatokunbo Awodele: Yes, you are. So, the floor is yours, sir. And if you could please state - if you can verbalize your - any conflict, your name, who you are, any conflict of interest for the recording, which we're ...

Dr. Aaron Farberg: I've got you covered.

Dr. Olatokunbo Awodele: Thank you very much.

Dr. Aaron Farberg: Yes, yes, yes. Well, first of all, thank you for the opportunity to speak here before the board. We really do appreciate all the Macs. There is continued effort to try to get this right, as you guys always are. I am Dr. Aaron

Farberg. I'm a double board-certified physician in both dermatology and micrographic dermatologic surgery, Mohs surgery. Next slide.

I have no conflict to report, nor any perceived conflict like many others here have. I don't make my primary income off of SRT, off of IGSRT, nor performing entirely Mohs surgery all day every day, which we can all see all of these as conflicts. Now, I have reached out to several of the radiation companies for more information, and I have also recently published a few articles on the topic of IGSRT. And I'm also made aware of all the goings-on here, as I'm a member of the DermCAC. I'm also the previous deputy chair of it. And I'm also on the board for the American Academy of Dermatology's Clinical Guidelines Committee.

So, you know, why am I interested in all this? Well, one of my research fellows had studied and published on IGSRT. So, like any good physician, I was cautious and perhaps even skeptical of the treatment. So, I wanted to sort of see the data, review the evidence, and most importantly, gain clinical experience.

And my interest in all these treatments actually started a long time ago during my medical training, which was many years at the University of Michigan, so go blue, for medical school and plastic and reconstructive surgery residency where I spent seven years as a lead within the craniofacial research laboratory, which is actually a combined laboratory with the renowned radiation oncologist Ted Lawrence, past president, ASCO board member, ASTRO president, I mean, and he's really one of the founding fathers of radiation therapy for head and neck cancer, another topic that I've published and studied on during my time there.

So, fast forwarding now, you know, I have several of my own medical dermatology practices, but I'm most proud of that we're directly affiliated with our own dermatology residency training program where we train three residents here, nine residents total. And I can assure you that our dermatology residents all receive great education and clinical experience with SRT, with image-guided SRT, as well in the clinics.

And I believe others will be speaking to the training points as well as the position from the American

Academy of Dermatology. But the idea that SRT should only have been utilized by radiation oncology or require some over-specialized mandated training, when we dermatologists have been providing safely and effectively treating tens of thousands of patients, hundreds of thousands over the decades, is just - that's preposterous.

Furthermore, I'll say, given the large private equity-backed radiation oncology rollup down the street from me, apparently performs the same IGSRT with even more visits, 26 according to my patient who had it done. So, I have doubts that costs will be conserved by one specialty over another. In any case, you know, I also feel like I should probably explain why I'm speaking a little off, why I'm speaking the way I am unclearly.

You see, I had a surgery for my jaw in the past few months, and it was functional issue. And so, after trying several other interventions over my lifetime, I needed to proceed with surgery to fix my breathing and my bite occlusion, which brings me to a very important point. Anyone who paid attention in medical school, particularly the surgery clerkships, understands that surgery should

be a last intervention, not first line.

Now, you know, right now, I wish I hadn't undergone my surgery, but, you know, hopefully it'll get better. Of course, you know, surgery and necessity doesn't include things like trauma, surgical emergencies, functional necessity and other certain elective procedures, but, you know, the point here is as good surgeons, you know, we know when to call other doctors, or just use other therapies first.

You know, there's other ways of managing things and, you know, surgeons are performing less and less in favor of their own medical management of disease, or by calling colleagues such as, you know, interventional radiology to place a drain, instead of cutting them open, or interventional cardiology to fix a valve, you know, or - you know, and there are situations in medical oncology to utilize immunotherapy.

So many times I see people try to operate, most surgeons operate on a lesion they shouldn't be touching, and the medical oncologists could do a much better job. All of these things instead of surgery. So, again, it really is important to maintain access and availability. And I for

one really sure hope we have progressed from Mohs surgeons performing 20 plus Mohs surgeries every day as the only skin cancer treatment option available by the time I'm a 65-year-old Medicare beneficiary, and I'll probably have to have lots of skin cancer treated because I've had enough sunburns as a child too.

Now, and I'm also working on this, by the way, not just with IGSRT here, but really also I'm a PI on a study for intralesional immunotherapy for skin cancer, which by the way may be more impactful and also probably going to cost more than Mohs and IGSRT combined, but it's going to be the right thing for patients.

So, you know, you see other fields are being allowed to advance. And this LCD is restricting specifically to Medicare beneficiaries seeking dermatologic care. As with IGSRT, we dermatologists can actually utilize the therapy to help our patients.

All right. So, with the brief time I've got, I've got to go through these slides. You know, my goal is to really make the points that I've made, you know, and include references that you can actually, you guys, you're the

medical directors, you review the data yourselves, you know, and perhaps some of the citations that were missed. You know, this is SRT. You guys know what it is. Next slide.

Right. What are all the benefits of IGSRT? I think somebody said, wow, it sounds really great. Well, you should talk to some of the patients. I think you're going to get a bunch of letters from them too. It really is a very high satisfaction here. This is what my patients get to enjoy. And again, if it was perhaps you on the other side sitting in the patient chair, you'd want this at least as an option, and it should be discussed as opposed to a patient being forced into only Mohs surgery as the only option because, you know, perhaps their own possible conflict of interest. Next slide.

Yes, so, you know, this is - here's an ultrasound, what it does in case you missed it. It was the primary imaging method that we used at the University of Michigan. We had several on every floor of the hospital because we all knew how to use them. Visualization really allows for monitoring these lesions, and thus you can have adaptive therapy, just like my wife who had it done every time she

went into her obstetrician during her pregnancies. And she also received an ultrasound at every visit, including the weekly ones we had for our high-risk twins that were born. Every week, an ultrasound billed and paid for. I'll note, I never found any published evidence or necessity for it, but it was just common medical sense, which prevailed and was paid for. Next slide.

You know, here's the goal to really kind of set the stage for, you know, what we see clinically, you know, but that there is data and several published articles that, you know, were or were not cited in the LCD. You know, IGSRT has a 99% cure rate. It's in published data, and we see it clinically as I've told you before. Next slide.

And no, it doesn't matter what type of non-melanoma skin cancer it is. And importantly, you know, the treatment care is quite durable. You know, you see two, four, you know, five and six years, you know, this is an effective treatment. And, you know, we know that from not just our clinical experience, but also from some of the published data. Next slide.

So, you know, here's a published study that illustrates an

issue that previous SRT studies not utilizing ultrasound, you know, revealing SRT to be inferior to IGSRT, which, you know, it makes logical sense, of course. You know, previously, SRT was performed in a variety of ways, with a variety of devices. Similarly, Mohs can be done and is quite operator-dependent, which explains why perhaps, you know, why the study on the right showed IGSRT as superior.

Now, is that true always? Maybe, maybe not, but it means that, you know, they're at least equivocal in efficacy and need to be discussed. We all can't go see the world's best Mohs surgeon up in the Northeast, you know, and we know that there is a skin cancer treatment access problem. And oh, by the way, the Mohs College, in limiting the training of these surgeons, you know, has unfortunately made this problem worse.

And speaking of access, do you know how many active SRT devices there are in the NGS area? It's not a perfect science, but when you look at who and what is billing according to CMS and Medicare in your area, it appears that there's only six machines. There's only six locations in four States across the entire NGS jurisdiction.

So, you know, where is this explosion that people had talked about earlier? Oh, and in the 19 States, for the other MACs that are all participating in this LCD - or I'm sorry, for the other States, there's only 19 States that are actually - you know, have or offer SRT. So, you know, we really do have, I think, an access problem. I mean, again, that's the numbers. Tell me there isn't. Next slide.

Dr. Olatokunbo Awodele: Sir, I just wanted to say you have about a minute left, so if you can...

Dr. Aaron Farberg: Oh, hot dog, I'll go fast. Sorry, I thought we had 15 minutes. I apologize. You know, retrospective cohort study looking at many non-melanoma skin cancer lesions, yes, high cure rates, yes, this is what we see, yes, it's retrospective, you know, but it's important data to review. It tells us that when you utilize imaging prior to modified radiation delivery, we may expect a 99% cure rate.

You know, importantly, it shows that other factors such as tumor location, gender, you know, have no impact on the outcome. And, yes, you know, I'm also a reviewer for top journals, and although, you know, there have been

comments criticizing the journal titles, you know, I'll also highlight that there's obviously politics involved in those journals, you know, no surprise. And I'll also highlight, hey, look, you know, those little changes can make a difference. Next slide.

You know, how often do you expect those changes with IGSRT? You know, about 40% of the time. Next slide. All right. Yes, sorry, you can go back. So, you know, again, now a skeptic can continue to argue that these changes, whether they're big or small, they may make no difference. And well, the published data on IGSRT says it does and that the efficacy and safety must come from somewhere.

You know, again, there was a previous speaker highlighting a JAAD article showing that, yes, there are small changes, but really, the conclusion was that they just don't think it was worth the cost. But, you know, if you're going to get those results, then you need to follow those protocols, you know. The IGSRT studies had imaging at every visit. So, the answer is, do you need it? Yes, until perhaps the NIH or a MAC or one of the other doctors out there perhaps does their own study to evaluate exactly

that. And you know what, I really hope we do do that because this can kind of settle everything once and for all.

You can click, click, click to the end. I guess I just want to get you to the references. I'd say my overall summary, I know we're talking about Medicare beneficiaries, So, this isn't Burger King, and patients can't just, "Have it their way." But if you are to undergo SRT, then I'd hope that the burger is safe, accessible, and at least cooked properly, which means image guidance is part of the SRT, superficial radiation therapy. Thank you, and again, I appreciate your effort to always try to get this right. Have a wonderful rest of your day.

Dr. Olatokunbo Awodele: Thank you very much, Dr. Farberg. And as I've said to everybody else, if you don't mind, could you please send these comments to us in writing, as well as the various literature that you feel support your position on this, which we might have missed, according to you. So, thank you very much. So, our next speaker is Dr. Janine Hopkins.

However, before Dr. Hopkins starts, I just want to

announce that anybody who is online who would like to make comments in preparation, should please go ahead and put your hand up sometime during Dr. Hopkins' presentation so that we can see how many people we have online that want to make a public comment, and we can get ready to unmute you in order. So, thank you very much for heeding that.

So, Dr. Hopkins still does not appear to be online. So, I believe we'll skip Dr. Hopkins for now and go to the online comments. So, if there's anybody online who would like to make a comment about this draft LCD, could you please raise your hand using the raise hand function so we can see. Okay. (Crystal) and (Alicia), I do see one, Eric. So, if we can enable his microphone. Okay, Eric, you're unmuted. If you could please start by introducing yourself in terms of your full name, any conflict of interest, and then go ahead and give your comment. Thank you very much.

Eric Larson: Yes, thank you for your time. My name is Eric Larson. I am a radiation therapist with Dermatherapy Solutions. I have no conflict, other than I work in both the - have worked both in electronic brachytherapy and the SRT world. I've been doing this for over 12 years, and I'm seeing from the

patients that we have had, both good results.

This is a - the biggest piece with this is, as Dr. Chang mentioned, the updated information, updated studies that were not included in this LCD. But the other part is also the known cost factor. With electronic brachytherapy, it needs to have - we typically treat 8 to 10 fractions. The overall billing rate, the overall cost is reduced versus, you know, anything over than a three-stage Mohs, that type.

But the big piece is that it is a known cost. Once the patient comes in for the treatment, you know how much it's going to cost. With the other technologies, with some surgeries, once you get in there, you don't know if you're to need reconstruction, if you're going to need this other, you know, extra pieces that isn't mentioned in the initial cost as far as for just the amount of getting rid of the cancer.

You can get rid of the cancer, but then you have to recover - you have to deal with, as Dr. Farberg said, the result of that and how to fix it, and that adds just additional cost. So, I just want to strongly suggest that we

change the LCD to include EBT as it is a proven and growing line of research studies that show that it is effective and efficient. And I thank you for your time.

Dr. Olatokunbo Awodele: Oh, sorry, I was on mute. I was saying thank you, Eric, for - oh, I had a great presentation, too. Thank you very much, Eric, for your comments. If you could please send them in writing to us. At the end of all the presentations today, we will be listing the various ways that you can get your comments into us, but I really appreciate you speaking up today.

Eric Larson: Yes, I'll do that. Thank you.

Dr. Olatokunbo Awodele: And Dr. Hopkins - Thank you. I was saying that I didn't see anybody else raise their hands. And so, with Dr. Hopkins not being here yet, and we've reached out to her by email, we'll proceed to the next draft LCD, yes. So, the next draft LCD that we'll be discussing today, presenting today, is 39314, titled Off-Label Use of Intravenous Immune Globulin. And based on a reconsideration request received in December of 2024, the off-label use for IVIG for Susac syndrome has been rigorously evaluated, and off-label coverage has been

granted, thus expanding off-label use of this drug, IVIG. Next slide, please.

So, current treatment protocols typically employ a combination of high-dose corticosteroids and IVIG, particularly for patients with active or relapsing disease. The administration of IVIG at a starting dosage of 2 grams per kilogram over several days, followed by monthly maintenance doses of 0.4 gram per kilogram for six months, is a standard practice aimed at stabilizing the disease and preventing relapses, especially in cases where retinal involvement is severe. Clinical observations support its efficacy in reducing the frequency and intensity of relapses, aiding in the preservation of visual function, and minimizing neurological and hearing deficits. Next slide, please.

So, with that being said, are there any further comments on the off - we didn't receive any requests to present on this draft, by the way. But are there any further comments on the off-label use of IVIG online? Does anybody online want to make a comment on this draft? Okay, so if not, online comments are closed on the off-label use of IVIG, so thank you very much. If we can go to the next slide,

please.

The next draft is DRAFT-LCD-39297 titled Off-Label Use of Rituximab and Rituximab Biosimilars. And based on a reconsideration request received in February 2025, the following off-label uses of Rituximab for ANCA-associated vasculitis, also known as AAV, IgG4-related pancreatitis, and Susac syndrome, have been rigorously evaluated, and off-label coverage has been granted, thus expanding the use of Rituximab and Rituximab biosimilars off-label. Next slide, please.

Overall, Rituximab's B cell-depleting properties make it valuable for treating these complex autoimmune conditions, despite the challenges of limited high-quality evidence. Its use is guided by clinical experience and condition-specific needs, often reserved for cases refractory to standard treatments. So, when it comes to Susac syndrome, Rituximab is used in resistant cases of Susac syndrome, when patients do not respond adequately to corticosteroids and IVIG.

So, while there are no randomized controlled trials for Susac syndrome, anecdotal reports highlight Rituximab's

role in managing severe or breakthrough cases, often in combination with mycophenolate mofetil. Its use reflects clinical experience aiming for early aggressive treatments to improve outcomes. When it comes to ANCA-associated vasculitis, Rituximab is a key treatment for inducing and maintaining remissions in AAV. It has demonstrated comparable efficacy to cyclophosphamide, particularly in relapsing cases, evidenced by studies like R-A-V-E and M-A-I-N-R-I-T-S-A-N, or MAINRITSAN.

Its safety profile is favorable, with fewer long-term concerns compared to traditional therapies. Rituximab is recommended for severe or relapsing AAV, offering effective relapse prevention and reduction in glucocorticoid dependency. In IgG4-related disease, Rituximab is effective for patients with incomplete responses to glucocorticoids.

So, while beneficial, more robust trials are needed to establish its long-term efficacy and safety fully. But, as we mentioned above, these are diseases that occur in the population very few. So, it's difficult to get RCTs together. So, next slide, please. So, we didn't get any requests to

respond registration-wise, but we would like to know if there's anybody online who has comments on the off-label use of Rituximab and Rituximab biosimilars. Okay. So, not seeing any online, we will - oh, there is, okay. Dr. Wong, if you can please unmute.

Dr. Eric Wong: Yes, thank you.

Dr. Olatokunbo Awodele: Oh, there we go. We can hear you, sir. Could you just state your full name and any affiliations or conflict of interest? And you may proceed.

Dr. Eric Wong: Sure, my name is Dr. Eric Wong. I'm a neurologist and oncologist at Brown University Health. I have no conflict of interest regarding Rituximab. Now, the indication that you just mentioned, the IgG4-related disease, the ANCA-associated vasculitis, and Susac syndrome, the off-label use does apply to these specific inflammatory diseases, or are there additional ones that Medicare would allow for?

Dr. Olatokunbo Awodele: Yes, so the - thank you for that question. The draft LCD has an accompanying article which explains - which expands, it gives you all the various ICD-10 codes

and the CPT codes that are covered in this draft. So, I would recommend that you review that. And if it seems as if the disease that you're particular about is not represented, then you will have to follow the reconsideration process to ask for that, pending supporting literature.

Dr. Eric Wong: Okay. So, where can I find that list? Is it on the (Evian) website?

Dr. Olatokunbo Awodele: We are - this is NGS.

Dr. Eric Wong: Oh, okay. So, you said NGS.

Dr. Olatokunbo Awodele: So, if you go to ngsmedicare.com and go to our draft LCDs and search for this particular draft, when you click on that, it will take you to the Medicare website that will - the CMS website that will open up the document. And if you scroll all the way to the end of the document, you will see pinned to it the associated document, which is the article that I'm referencing. And you will click on that, and that will give you all the various diseases that are represented.

And also, if you go into the actual Rituximab LCD and read that, you will be able to see other diseases that are covered in this. We don't talk about all of them because they already exist. This is to expand and add these diseases. Yes.

Dr. Eric Wong: Okay, thank you for the clarification.

Dr. Olatokunbo Awodele: You're welcome, sir. Is there anybody else who has any comments online about this? Okay, so seeing none, we will close online commenting on this draft LCD. If we can go to the - so now I'm going to hand over to Dr. Janet Lawrence who will speak to this next draft. Dr. Lawrence?

Dr. Janet Lawrence: Thank you, Dr. Awodele. Good afternoon, everyone. I'll be presenting on Fluid Jet System Treatment for lower urinary tract symptoms for benign prosthetic hypertrophy. This session will explain the technology and its proposed benefits. After my introduction, Craig Gonzales from PROCEPT BioRobotics, will continue the discussion. Remember to raise your hand if you wish to contribute to discussion. We value your input. After this segment, we will again invite comments.

So, National Government Services, along with other Medicare administrative contractors, received a reconsideration request to revise the covered indication guidelines by removing the age requirement, prostate volume specifications determined by transrectal ultrasound, the need to void at least 125 CCs of urine, and the exclusion criteria of patient with known or suspected prostate cancer, or a prosthetic-specific antigen greater than 10 nanograms per milliliter, unless the patient has a negative prostate biopsy within six months of treatment. Additionally, it was requested to remove limitations concerning bladder calculi and body mass index. Next slide.

So, the indications of coverage are, treatment for lower urinary tract symptoms, BPH, which will be considered reasonable and necessary when performed once in patients with the following indications, including all of the following, prostate volume of 30 to 150 CCs by transrectal ultrasound, persistent moderate to severe symptoms despite maximal medical management, including all of the following, International Prostate Symptom Score, IPSS of greater than or equal to 12, maximal urinary flow rate

of less than or equal to 15 milliliters per second, failure, contraindication, or intolerance to at least three months of conventional medical therapy for lower urinary tract symptom, BPH, and for example, alpha blockers, phosphodiesterase inhibitors, finasteride, or dutasteride. Only treatment using an FDA-approved clear device will be considered reasonable and necessary. Next slide.

The limitations. The following are not - are considered not reasonable and necessary. So, a body mass index of greater than or equal to 42 kilograms per meter squared, known as suspected prostate cancer based on NCCN Prostate Cancer Early Detection Guidelines, or a prostate-specific antigen greater than or equal to 10 nanograms per ml, unless the patient has had a negative prostate biopsy within the last six months.

Bladder cancer, neurogenic bladder, bladder calculus, or clinically significant bladder diverticulum. Active urinary tract or systemic infection treatment for chronic prostatitis, diagnosis of urethral stricture, meal stenosis, or bladder neck contracture, damaged external urinary sphincter, known allergy to device materials, and inability to safely stop anticoagulants or antiplatelet agents

preoperatively. Next slide.

So, now we will hear from our registered speaker, Mr. Gonzales, and I see that he has raised his hand. And Mr. Gonzales, can you unmute yourself, please?

Craig Gonzales: Yes.

Dr. Janet Lawrence: All right, you're ready to go.

Craig Gonzales: All right, thank you, Dr. Lawrence, Dr. Awodele, and the NGS Medical Committee for giving us time to present on this topic. We appreciate the work that the committee has done in working on this draft LCD. My, if we flip to the next slide, disclosures. I am an employee of PROCEPT BioRobotics. We are the manufacturer of the AquaBeam and our newer Hydros systems, which is used in the aquablation procedure or fluid jet or transurethral water jet ablation of the prostate. Next slide, please.

So, again, thank you for the work that you guys have done on the draft LCD. We are requesting that the language in the draft LCD that requires the prostate size to be measured by transrectal ultrasound in Indication 1.A, as

Dr. Lawrence showed in some of her previous slides, that that requirement of the TRUS being used to measure gland size be removed.

Our rationale is that we would like, in advocating for both our patients and our physicians across the country, reduce inconsistencies between the MACs, and we'll walk through a couple of examples where the other MACs are making some of the same changes, but they have removed this TRUS requirement. The other thing is that there are other methods that are adequate in measuring prostate size, and we would like to allow the physicians the flexibility in choosing the methods that's best for them and best for their patient. If you could, next slide, please. So, again - actually, if you could click it one more time. There might be some builds in there.

So, on the indications, Dr. Lawrence sort of walked through these. Once again, thank you very much for removing that voided volume on 125 CCs on QMAC. That, I think, was - will be very helpful for our patients and for our physicians. And our question really is keeping the prostate volume size as measured by transductal ultrasound in the indications, which would mandate that

there is a preoperative transductal ultrasound in order to establish the prostate volume.

So, if we could switch - flip, I think maybe two more slides, there's the limitations. We have no issues with the existing limitations as a - and if we could just go on to the next slide. So, what we're I'll walk through with you here is just some examples. We'll get some examples here. So, First Coast and Novitas earlier this year also released drafts. These drafts went active on April 6th of 2025.

The indications and limitations match everything that is being proposed here in the draft for NGS's LCD. The one thing that's highlighted down at the bottom is that they did keep the prostate volume sizes in as 30 to 150 CCs, but they did remove the requirement that that sizing be done by TRUS. The next - one more slide.

The other MACs that we've been tracking, CGS, Noridian, and WPS, just within the same time period, have also released draft LCDs. You can see CGS's, Noridian's, and WPS's, the draft LCD numbers and titles when they were posted up there. And then you can see down at the bottom - this is a snapshot of Noridian's. But all of them,

again, match the same covered indications and limitations, with that one exception of the prostate volume 30 to 150 CCs. And none of these MACs in their draft LCDs are asking - are requiring that the gland size can be done by TRUS. Next slide, please.

So, again, just to wrap it up and kind of reiterate what we're asking is that we would like for that TRUS requirement in Indication 1.8 to be removed, again, really just to reduce that inconsistency between the MACs across the country and allow our physicians to choose the best methodology for them and their patients in terms of sizing up that gland size.

We don't disagree with the 30 to 150 CC gland size, but we would like to maintain consistency across the MACs, and we would like our physicians and our patients to choose the sizing methodology that's best for them. So, again, thank you for your time and for listening, and we will be submitting these comments in writing at the conclusion of the call.

Dr. Janet Lawrence: Thank you so much for that, Mr. Gonzales, and you were one step ahead of me with how you will be

presenting. So, are there any comments from the audience? Okay, seeing none, I will turn things back over to Dr. Awodele.

Dr. Olatokunbo Awodele: Well, thank you very much, Dr. Lawrence. We have Dr. Hopkins on the line, so we're going to go back to her presentation. So, Dr. Lawrence, if you could please - I mean, sorry. Dr. Hopkins, if you could please use the raise hand function of Teams so we can identify you and enable your mic. Oh, there it is.

Hello.

Dr. Olatokunbo Awodele: Oh, hi, Dr. Hopkins. We can hear you loud and clear.

Perfect. Thank you.

Dr. Olatokunbo Awodele: So, if you could begin your presentation stating who you are and any conflicts of interest, we would appreciate that. Thank you very much.

Dr. Janine Hopkins: Great. Thank you very much. Yes. Thank you, everyone, for gathering today and discussing such

important matters as our patients' rights to receive optimal care. So, I'm a board-certified dermatologist. I've been in practice going on 29 years, and I have two locations, one in Monroe, Louisiana, and one in South Lake, Texas.

And as a dermatologist, it's been a large part of my career to treat skin cancer. During my residency program, we trained in both the Mohs surgical technique where we would identify the malignant lesions, excise them, and then use different flaps and graft techniques after clearing the margins. But also in the 1990s, during my residency, we did train in radiation therapy as another treatment modality to cure cancer without surgery, which was a very important option for those that were not good surgical candidates.

But like most of my colleagues, when I started my practice, and this was in 1996, there was no way for me to bring the radiation technology into a clinical office setting. And it really wasn't until about a decade ago that certain companies had worked with engineers and physicists to design devices that could now be installed in clinical office settings, allowing us to have a non-surgical

treatment option for the most common cancers, which are basal cell and squamous cell carcinoma.

So, if you'll advance my slides. I don't know if I have a non-disclosure slide because this was for a medical conference when I prepared this lecture, but I don't have any invested interest in any companies in this industry. I do work with SkinCure Oncology as a - basically, a company that allows us to, you know, have access to a team, rounds, as well as the devices, but no disclosures or conflicts.

So, just a quick overview about the burden of skin cancer. It is becoming a higher prevalence in different countries such as the U.S. and Australia. It's the number one cancer right now among people in the U.S. will see increased incidence of this, about 13% over the past years. So, the global burden is quite high in our next slide.

And I'm just going to kind of quickly go through these. We can even really quickly go past the three main types of skin cancer, basal cell, squamous cell, and melanoma. Basal cell is the most common. You can see it was - actually stop on that previous slide right there. We can go

back. These lesions often occur on very cosmetically-sensitive areas of the face. So, the ear is a complicated area for the surgery.

For 20 years of my practice, I did these surgical procedures. The lip is extremely difficult. In this gentleman, this would have been an excessive wide wedge excision of his lower lip. And for the gentleman on the helical rim of the ear, that could have resulted in a permanently notched ear. So, sometimes these lesions are large. They're complicated.

On the next slide is just a quick overview of the options that we currently have available. And the surgical options are the most commonly performed procedures, most surgery, several million of these cases a year, taking care of these millions of malignant lesions. And basically, you know, and again, this is treatment I've employed in my practice for about 20 years.

But unfortunately, there are a lot of patients who are not good surgical candidates. You know, like the gentleman we just saw, the lesion on the lip. And then, you know, what are our other treatment options that are non-

surgical? There's traditional radiation. There's, you know, electron beams that can be modified to target cancers on skin, but these are not specifically designed to treat skin cancer lesions.

We have immunotherapy and chemotherapy, which I do incorporate into my treatment plans. And now the image-guided radiation therapy is what we're specifically discussing today. In my medical opinion, this has been a complete game-changer on allowing us to identify which lesions are best amenable to superficial radiation therapy. And because of this ultrasound guidance, we are now able to achieve a very high cure rate of 99%, and I'll explain that further on the next slide.

Superficial radiation therapy's actually been around for several decades. Initially, this was performed with, you know, targeting these malignant lesions using radiotherapy. We know these low energy photon radiation devices can cause cellular damage and basically result in mitotic catastrophe and cell death. And thankfully, the healthy skin cells are able to regenerate when we're doing fractionated treatment, and that allows us to basically target malignant cells, destroying

them and letting healthy skins repopulate the area.

What has improved the cure rate from what was around 94%, and we can see on our next slide, is the ultrasound guidance which was incorporated into this protocol. So, now we're looking at using a high-resolution dermal ultrasound that actually allows us clinicians to very easily and clearly visualize the tumor depth.

And this is extremely important because tumor depth is going to allow us to determine, first of all, is this even a tumor that is a minimal to radiation therapy, to superficial radiation therapy? We know that there's a rate-limiting depth and it's three millimeters. If a lesion is less than three millimeters as determined on high-resolution dermal ultrasound, then we know that we can achieve the high cure rates that we're getting with this procedure. So, in other words, this is allowing us to correctly select the tumors that are going to respond well to this modality.

On the next slide, we can look at a comparison between ultrasound-guided versus non-ultrasound-guided radiation therapy. This is from a study that showed with

IGSRT using ultrasound to determine the depth of the lesion before starting treatment, and to monitor it during treatment, we were achieving 99% cure rates versus a comparison to the 94% cure rate we were receiving with non-guided SRT.

So, we know that with ultrasound, we're going to get a better cure rate because we are correctly selecting the patients and the tumors that are going to respond well. And of course, it also allows me to assure the correct dose. And I'll explain that further in a couple more slides.

Dr. Olatokunbo Awodele: Dr. Hopkins, this will be a nice break for me to tell you that you have five more minutes.

Dr. Janine Hopkins: Perfect. I can do it, and I appreciate the heads-up because I can be a long talker. Okay, so quickly in this photograph here, this is what the ultrasound looks like. We can see the white shiny layer is the epidermis, and then the green is the healthy skin. What's separating the white from the green is this dark hypoechoic cloud. Skin cancer actually does not reflect ultrasound back to the transducer, so therefore we're going to see this dark image where the tumor is occupying the space. And that

allows us to correctly measure the depth.

On the next slide, we can see that this tumor, again, is within 2.1 millimeters. And so, from that, we know that we can treat this at 100 kilovolts with 20 fractions to get to that 99% cure rate, because it's less than the 3-millimeter maximum depth. We'll go again to the next slide. And again, we can skip that one, and we'll kind of go through these a little more quickly.

For my practice in particular, I follow the guidelines of care. They've been published in the medical literature, and we use these guidelines where if it's less than 1.5 millimeters, I can use a lower energy of 70 kilovolts. If it's greater than 1.5 down to 2.5, then I'm going to use 100. And here's something that's extremely important. If it's greater than three millimeters, this is not the treatment of choice.

I know that those tumors exceed the maximum depth, and therefore I'm going to offer patients either combination therapy. We'll incorporate a hedgehog inhibitor or one of the immune therapy drugs that are FDA-approved. We have four to choose from. And then

we're able to pharmacologically shrink these tumors to a depth of around 2.5 to three, and then treat them appropriately with radiation therapy. Next slide.

So, again, the ultrasound gives us the knowledge on, is this a tumor that we can adequately and confidently treat with radiation therapy? Or is it a tumor that exceeds the maximum depth? So, again, that is important information for us to determine. In addition to that, next slide, we often are using these ultrasounds during treatment. This gives us a real time evaluation when they come in for their treatment on the tumor burden, it sometimes is going to give us guidance on maybe we should back off on the kilovolts, or maybe we need to go up on kilovolts so we can, with real knowledge, during real time using ultrasound guidance, make these smart decisions.

The final assessment, we can go to the next slide, is at least eight to 10 weeks after treatment, we're going to use ultrasound guidance to confirm that the tumor is clear. And on this example, and I'll just quickly give you a few more, if I have a few more minutes, this man had two malignant lesions. They were within a centimeter of each

other. Instead of going through radical surgery, we cured both lesions under one treatment area. So, two treatments, two cancers for the quote price of one, if you want to say that. We had them both under treatment and both were completely cured using the 20 fractions of IGSRT.

And on the next slide, you can see that we weren't just seeing healthy skin on the surface, but now post-IGSRT, the ultrasound has confirmed that the area is filling in with nice, healthy, green, iridescent skin. Another example on another slide is this gentleman's scalp with a large tumor. This patient is on anticoagulants. He's immunocompromised. He's wheelchair-bound. Surgery was not an option for this gentleman because of those underlying comorbidities. And thankfully, he had the choice and the option of having ultrasound-guided IGSRT, with a complete cure of this squamous cell carcinoma.

On the next slide, I believe we've got a gentleman, yes, this gentleman had already had three Mohs surgeries. Over his lifetime, he had had - and I will tell you, between my two practice locations, and I thought we had a lot of skin cancer in Louisiana, but I've been shocked by the

amount in Texas, but it is extremely common for at least over 50% of my patients to come in, and they've already had multiple Mohs surgeries, and they're really looking for a non-surgical cure to save them through some of the pain and agony that they've endured.

As an example, this patient had already had multiple Mohs surgery. He had a recurrent basal cell carcinoma. He neglected further treatment because he did not want to go back to the operating room, and finally when he discovered he had an alternative, we were able to cure this with IGSRT.

On the next slide, here's his ultrasound showing that we have cured the cancer. It's filling in nicely with green, healthy, iridescent skin, as well as you can see from his clinical photographs, the skin healed beautifully with healthy skin. Again, remember, we're not replacing cancer with scar tissue with this modality. We're literally destroying cancer and letting healthy skin repopulate the area.

I believe that's my conclusion. I hope I made it in the 10 minutes. Oh, there was this case. If we have one second, I'll

just - how many more minutes do I have?

Dr. Olatokunbo Awodele: You're right at it, but you can go ahead and talk about the case. That's fine.

Dr. Janine Hopkins: Okay, well, I want to tell you because obviously this wonderful little 83-year-old lady was not a surgical candidate. What she thought was a rash on her eyelid and cheek and had been putting cortisone cream on it for over a year, presented to me and this entire lesion area from her right upper eyelid to temple and down into the mid-cheek was all squamous cell carcinoma.

The one large lesion that was nodular and bleeding was what brought her in to see me, but all of that was cancer. And prior to having image-guided radiation therapy, I could have not offered her any options other than going on something systemic, with only about a 20% complete clearance rate. Those are immune therapy drugs, and surgery was certainly not an option for her.

And the final case here is a younger woman in her 50s who came in with what was thought to be a stye on her eyelid, over a year worth of antibiotic ointment. And when

she presented to me, this is a basal cell carcinoma. For her, the option of surgery was just not an option. She was terrified to have her eyelid surgically removed, and you can see the beautiful result we got with image-guided radiation therapy.

So, I just am passionate about this because now I've cured over 1,000 skin cancers using this modality. The ultrasound is an extremely important part of it because it gives us knowledge, and knowledge allows us to choose the correct lesions, making sure we're going to give that patient the best outcome. So, I believe that concludes my lecture or discussion, and I appreciate everyone's attention, and look forward to any comments and conversation to continue with this topic.

Dr. Olatokunbo Awodele: Thank you very much, Dr. Hopkins. And we've requested that all presenters please send us a written copy of their comments, including any literature that you may have to support such comments. Thank you very much. And so, I'd like to thank everybody for your active engagement and insights today. Your contributions play a crucial role in enhancing our policies and practices.

And we invite comments, even after today's meeting, through our contact channels, which would be that to comment on any of these proposed LCDs during the official comment period, which commenced May 15th, 2025, which is when we first put these drafts online, and ends June 28th, 2025. So, please click on the Submit Public Comment button on the proposed LCD in the Medicare Coverage Database.

You can also email us at PartBLCDcomments@Anthem.com. Notice it says at anthem.com. And you can also send your comments in by mail by addressing them to National Government Services, Inc., LCD Comments, PO Box 7108, Indianapolis, Indiana, 46207-7108. So, we'd like to thank everyone for taking the time out to attend our open meeting for June 2025, and I'd like to wish everybody a great rest of your day. Thank you very much, and you can disconnect at this time. Thank you.

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