Meeting Details	
Meeting Date and Time:	June 10, 2025, 3:00 p.m. - 5:00 p.m. ET
Facilitator:	Dr. Meredith Loveless

Disclosure Regarding Call Transcript

Due to unforeseen technical difficulties, the system was unable to record or transcribe the call/presentation held on 6/10/2025. As a result, a full transcript is not available.

In the interest of transparency, we have provided a summary of the key presentations and discussions to the best of our ability. This summary reflects the main points and topics covered during the session, based on available notes and participant input.

We apologize for any inconvenience this may cause and remain committed to maintaining accurate and complete records in the future.

Agenda

- Policy overview (Dr. Loveless)
- Presentation by Dr. Robert Haber
- Presentation by Dr. Brent Moody
- Presentation by Dr. Jacob Scot
- Rob Burnside
- Presentation by Dr. J Cheng

Dr. Meredith Loveless

General Information

- **Presenter**: Dr. Meredith Loveless, Chief Medical Officer, CGS Administrators.
- **Event**: Open Draft LCD Meeting for Jurisdiction 15 (KY & OH).
- **Date**: June 10, 2025.

Disclaimer

- The presentation is a general summary and not a legal document.
- Providers are responsible for correct claim submissions.
- Medicare policies change frequently; official documents should be consulted.

Draft Local Coverage Determinations (LCDs) Discussed

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1. **DL38378** – Fluid Jet System for Benign Prostatic Hyperplasia (BPH) (revision).
2. **DL40179** – Superficial Radiation Therapy (SRT) for Nonmelanoma Skin Cancers (NMSC).

DL38378 – Fluid Jet System for BPH

- **Requested Revisions**:
    - Remove age requirement (already done).
    - Remove prostate volume and voided volume requirements.
    - Remove exclusion criteria for prostate cancer, PSA >10, bladder calculi, BMI.
- **CGS Decisions**:
    - Removed transrectal ultrasound requirement.
    - Retained prostate volume limit (150 mL).
    - Retained exclusions for PSA >10, bladder calculi, BMI.
    - Qmax retained as a valid measure for urinary retention.

DL40179 – SRT for NMSC

- **Covered Indications**:
    - Low- or high-risk BCC/SCC or SCC in situ.
    - Patient must be a nonsurgical candidate (e.g., surgery causes loss of function, morbidity, poor cosmesis, or patient refusal).
- **Limitations**:
    - **HRUS (High-Resolution Ultrasound)** use with SRT is not considered reasonable or necessary.
    - **Electronic Brachytherapy (EBT)** is not supported due to insufficient long-term data.
    - **SRT not covered for**:
        - First-line treatment in surgical candidates.
        - Advanced BCC/SCC.
        - Tumors >4 cm or >6 mm deep.

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        - Aggressive morphology or perineural/perivascular invasion.
        - Very high-risk SCC.
- **Qualified Providers**:
    - Must have training from accredited residency/fellowship in radiation oncology or dermatology.
    - Facilities must meet federal/state radiation safety and supervision standards.

Summary

- SRT is supported for non-surgical NMSC patients.
- HRUS and EBT are not supported due to lack of sufficient evidence.

Open Comment Period

- **Dates**: May 15 – June 28, 2025.
- **Submission**:
    - Use comment form PDF.
    - Email to CMD.INQUIRY@cgsadmin.com.
    - Include full-text PDFs of supporting literature (no abstracts or in-press articles).

Dr. Robert Haber

What is IGSRT (Image-Guided Superficial Radiation Therapy)?

- Advanced form of superficial radiotherapy using image guidance.
- Allows adaptive treatment based on tumor response and anatomy.
- Customizes field margins and doses for safe, effective treatment.
- Enables real-time decisions during therapy (continue, adjust, or stop).

Benefits of IGSRT

- Over **99% cure rate**.

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- **Noninvasive**, **painless**, and **no downtime**.
- No need for local anesthesia.
- Patients can maintain daily activities and medications.
- Treats multiple lesions simultaneously.
- Ultrasound guidance provides visual reassurance.

Technology and Imaging

- Uses **High-Resolution Dermal Ultrasound (HRDUS)**:
    - Visualizes and measures lesions throughout treatment.
    - Enables adaptive dosing and precision targeting.
    - Aligns with ALARA principles (minimizing radiation exposure).

Clinical Case Example

- 81-year-old male with nodular BCC.
- Treated with IGSRT over 7 weeks.
- Experienced mild skin changes (erythema, ulcers).
- Achieved **No Evidence of Disease (NED)** at 4-month follow-up.

Efficacy and Safety

- **99%+ cure rates** for BCC, SCC, and SCCIS.
- **99%+ patient satisfaction**.
- **0.2% recurrence** in over 120,000 lesions.
- Supported by **15+ peer-reviewed publications**.

Long-Term Outcomes

- Freedom from recurrence (FFR) rates:
    - 2 years: 99.68%
    - 4 years: 99.54%
    - 5 years: 99.41%
    - 6 years: 99.54%

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Comparative Clinical Studies

- IGSRT showed **statistically superior local control** vs. non-image-guided SRT.
- Outperformed **Mohs Micrographic Surgery (MMS)** in 2-year recurrence rates.
- HRDUS imaging led to adaptive changes in ~40% of cases.

2024–2025 Large-Scale Studies

- Over 20,000 lesions analyzed.
- FFR rates remained above 99% across 2, 4, and 6 years.
- No significant impact of tumor location or sex on outcomes.
- Tumor stage affected outcomes slightly, but all remained >99%.

Daily Imaging Importance

- 92% of lesions showed daily depth fluctuations.
- 40% required treatment adjustments.
- 83% of lesions were high-risk per NCCN 2024 guidelines.

Conclusion & Guidelines

- IGSRT is **safe, effective**, and offers **excellent cosmetic outcomes**.
- Can be considered a **first-line treatment** for selected NMSC cases.
- Dermatologists are best suited to administer IGSRT.
- Treatment choice should consider patient preferences and tumor characteristics.

Dr. Brent Moody

- **Support for LCD**: The American College of Mohs Surgery (ACMS) supports the Local Coverage Determination (LCD) as written.
- **Patient Protection**: The LCD includes reasonable safeguards to protect patients.
- **Consistency**: The proposed LCD closely mirrors existing LCDs for Mohs Micrographic Surgery, which ACMS has previously supported.
- **Need for Regulation**: Due to the high prevalence of skin cancer, LCDs are essential to:

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    - Maintain program integrity.
    - Prevent unproven or medically unnecessary services.
    - Protect CMS from abusive billing practices.
- Peer-Reviewed Publication: A new study on SRT/IGSRT was published in the Journal of the American Academy of Dermatology (JAAD), August 2024 edition.
- Study Focus: Analyzed national Medicare trends in dermatology radiotherapy from 2016 to 2021.
- Authors: Drs. Christian Gronbeck, Neelesh P. Jain, Albert E. Zhou, and Hao Feng from the University of Connecticut School of Medicine.
- Journal Prestige:
    - JAAD holds the highest Impact Factor among dermatology journals.
    - Known for rigorous peer-review standards.
    - Not open access – publication is merit-based, not pay-to-play.
- **SRT is not considered first-line therapy**.
- **IGSRT offers no proven advantage over standard SRT**.
- **Use of SRT is not restricted** when it is **clinically indicated**.
- **Documentation is required** to justify the use of SRT, but no significant clinical limitations are imposed.
- **SRT is considered reasonable and necessary if:**
    - The patient has **low-risk or high-risk basal cell carcinoma (BCC)** per NCCN®, ASTRO, and AAD guidelines **and is a nonsurgical candidate**.
    - The patient has **low-risk or high-risk squamous cell carcinoma (SCC)** per the same guidelines **and is a nonsurgical candidate**.
    - The patient has **cutaneous SCC in situ**, again per NCCN®, ASTRO, and AAD guidelines, **and is a nonsurgical candidate**.
- **Primary Treatment Options for Low-Risk Basal Cell Carcinoma (BCC)**
    - **Surgical Treatments**:
        - **Curettage and electrodesiccation (C&E)**

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        - **Shave removal**
        - **Standard excision** with 4-mm clinical margins and postoperative margin assessment:
            - **Positive margins** → further action needed
            - **Negative margins** → no further treatment
    - **Radiation Therapy (RT)**:
        - Recommended for **non-surgical candidates**
- **Non-Surgical Modalities (for superficial BCC without dermal extension):**
    - **Topical imiquimod** *(preferred)*
    - **Topical 5-fluorouracil (5-FU)** *(useful in certain circumstances)*
    - **Photodynamic therapy** (e.g., topical ALA, porfimer sodium – *category 2B*) *(useful in certain circumstances)*
    - **Cryotherapy** *(useful in certain circumstances)*
- Of all these options, Radiation Therapy is by far the most expensive.
- Why are we seeing this trend toward utilization of the most expensive option?
- LCD Statement: High-resolution ultrasound (HRUS) used to guide superficial radiation therapy (SRT) or assess lesion reduction is not considered reasonable or necessary.
- Lack of Evidence: The LCD states this use of HRUS is not supported by the literature.
- ACMS Position: The American College of Mohs Surgery supports this provision of the proposed LCD.
- Literature Review: ACMS agrees that the LCD includes a comprehensive review of the literature, which does not support the use of ultrasound in this context.
- Concerns About SRT/IGSRT Evidence Base
    - Low-Quality Publications:
        - Studies are published in low-impact journals (impact factor 2.2–4.4).
        - For comparison, JAAD has an impact factor of 11.1.

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        - Journals are described as “pay to play” with quick turnaround for lower-quality manuscripts.
    - Author Conflicts:
        - Many studies are authored by individuals with industry ties, raising concerns about bias.
    - Methodological Flaws:
        - Studies are not randomized.
        - Inconsistent reporting of tumor stage and risk factors.
        - No standardized reporting of adverse events.
        - Patients who didn’t complete treatment were excluded from analysis.
        - No intention-to-treat analysis, allowing potential manipulation of outcomes.
- General Observation:
    - If IGSRT results were truly as strong as claimed, why aren’t they published in top-tier dermatology or oncology journals?
- Critique of IGSRT Study Cited by Proponents
    - Scientific Concerns:
        - Not randomized
        - Retrospective chart review
        - No standardized treatment protocols
        - No standardized adverse event reporting
    - Methodological Flaws:
        - Only included patients who completed 20 radiation fractions, excluding those who:
            - Experienced adverse events (AEs)
            - Had disease progression during treatment
        - No intention-to-treat analysis, allowing for cherry-picking of favorable outcomes

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    - Conflict of Interest:
        - Industry ties among authors raise concerns about bias
- Critique of a Frequently Cited IGSRT Study
    - Scientific Validity:
        - Not published in an oncology journal; instead, appeared in a geriatrics journal with no other interventional oncology articles.
        - Rapid turnaround, pay-to-play publication model raises concerns about peer-review quality.
        - Unclear reviewer qualifications, particularly regarding experience in cutaneous oncology.
    - Conflict of Interest:
        - At least one author had undisclosed industry ties.
    - Methodological Issues:
        - Non-randomized, not prospective.
        - Retrospective chart review with no standardized treatment protocols.
        - No standardized adverse event reporting.
        - Excluded patients who did not complete 20 radiation fractions, potentially omitting those with adverse events or disease progression.
        - No intention-to-treat analysis, allowing for cherry-picking of favorable outcomes.
        - Used data scraping, a method not validated for assessing skin cancer recurrence.
    - General Observation:
        - While the study touts large patient numbers, this amplifies methodological flaws rather than correcting them.
- Critique of Ultrasound Guidance in SRT/IGSRT
    - Lack of High-Quality Evidence:
        - No high-quality studies directly comparing SRT vs. IGSRT.

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        - Literature on ultrasound use is vague and lacks validated protocols.
    - Clinical Considerations:
        - Radiation fields can be set by clinical examination alone.
        - Skin cancers treated with SRT are typically superficial, so 1 mm measurement differences are clinically insignificant.
        - Tumor size does not change daily, so field expansion is unnecessary.
        - No evidence supports reducing radiation dose based on tumor response.
    - Technical Limitations:
        - No validated method for assessing tumor depth via ultrasound.
        - No correlation established between ultrasound depth and microscopic invasion.
    - Experimental Status:
        - At best, IGSRT should be considered experimental due to lack of robust evidence.
    - Support for LCD Conclusion:
        - Agrees with the LCD authors: the overall quality of evidence for SRT in BCC/SCC is low, citing:
            - Nonrandomized, single-center studies
            - High risk of patient selection bias
            - Variability in SRT techniques
            - Lack of direct comparison to standard treatments like Mohs surgery
    - Despite lack of good evidence, Ultrasound guidance use has exploded.
- **Image Guidance & IGRT**
    - **Not medically necessary** for skin cancer; **external landmarks are reliable**.
    - **IGRT is designed for internal cancers** (e.g., prostate), not for NMSC.

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        - **American College of Radiology/ASTRO**: IGRT may be used in special cases (e.g., morbid obesity, proximity to critical structures, internal motion).
        - **Ultrasound guidance**:
            - **Not medically necessary**.
            - **Tumors are visible** and **do not change significantly day to day**.
            - **No validated protocols** for tumor depth assessment or adaptive therapy.
            - **No evidence** that ultrasound improves outcomes or allows safe dose reduction.
            - **ACMS supports LCD's restriction** on HRUS use.
            - Helps curb **abusive billing** practices.
            - **Ultrasound may be appealing**, but that doesn't make it medically necessary
- **Billing & Coding Concerns**
    - **G6001**: Dermatologists billing for **glutaraldehyde** ($110.08/use) is questionable.
    - **Eliminating ultrasound coverage** would also eliminate **inappropriate coding**.
    - **CPT 77280/85/90** (simulation codes):
        - **ACMS disagrees** with allowing these codes for SRT.
        - **Believes simulations are not medically necessary** for SRT.
        - **2021 data**:
            - Dermatologists: **13.08 claims/patient**
            - Radiation oncologists: **1.49 claims/patient**
            - Nearly **1:1 ratio** of SRT to simulation claims—suggests **waste/abuse**.
        - **CPT vignette** for 77280 describes complex oncology cases (e.g., metastatic prostate cancer), not superficial skin cancers.

Provider Qualifications

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- **Qualified physicians** must have training via **accredited residency/fellowship** in radiation oncology or dermatology with radiation experience.
- **ACMS supports** these requirements.
- **Consistent with Mohs LCDs**.
- CMS should be **selective in who can bill** for radiation services due to complexity and treatment options.

Electronic Brachytherapy (EBT)

- **LCD states** EBT is **not reasonable or necessary** for NMSC.
- **Lacks long-term efficacy and safety data**.
- **ACMS agrees** with this conclusion.

Support for LCD

- **Conscientious providers should welcome the LCD**.
- Helps ensure **appropriate billing** and **medically necessary care**.
- **Reduces abuse** while protecting access for legitimate providers.

Simulation Codes (CPT 77280/85/90) – Inappropriate Use in Dermatology

- **Not applicable in dermatology settings**:
    - Descriptions involve complex procedures (e.g., CT simulation, spinal metastases) not performed in dermatology offices.
    - **Over $2 million in equipment costs** are built into the RVUs—equipment dermatology offices do not possess.
- **ACMS Position**:
    - Billing these codes in dermatology is likely **inappropriate** and represents **waste or abuse**.
    - **"Close enough" billing is not acceptable**; if no accurate CPT code exists, **17999 (unlisted service)** should be used.
    - **ACMS encourages disallowing** any billing of 77280/85/90 with SRT.

Summary of ACMS Support for the LCD

- **Supports the LCD as written**:

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- **Preserves access** to SRT for appropriate tumors and patients.
- **Eliminates medically unnecessary and unsupported image guidance**.
- **Protects patients** from unnecessary and abusive billing (e.g., ultrasound).
- **Encourages ethical practice**—no reason for honest providers to object.

Dr. Jacob Scott

Overview

- Presentation by Dr. Jacob Scott, President of the Dermatology Association of Radiation Therapy.
- Focuses on deficiencies in the proposed Local Coverage Determination (LCD) for Superficial Radiation Therapy (SRT), particularly regarding **Image-Guided SRT (IGSRT)**.

Key Criticisms of Proposed LCD (DL 40179)

- **Outdated Evidence**: Ignores 11 peer-reviewed IGSRT studies published since 2023.
- **Search Bias**: Exclusion of HRDUS & HRUS terms led to omission of relevant studies.
- **Misrepresentation**: Bases conclusions on older SRT data, not IGSRT.
- **Selection Bias Misinterpretation**: Studies show IGSRT is effective even in high-risk patients.
- **Access Impact**: Over 120,000 patients treated with IGSRT since 2016; LCD would limit access for frail Medicare patients.

Medicare Protocol Violations

- LCD fails to meet Medicare Program Integrity Manual Section 13.5.3 requirements:
  - Lacks full description of service.
  - Incomplete evidence summary.
  - No clear target population or usage context.

Scientific Evidence Supporting IGSRT

- **Ladd Yu Protocol**: >99% cure and freedom from recurrence (FFR) rates in large cohorts.

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- **Daily Imaging**: 92% of lesions showed depth changes; 40% required dose adjustments.
- **Meta-analyses**: Real-time ultrasound significantly improves outcomes.

Flaws in LCD's Evidence Analysis

- Claims low-quality evidence due to nonrandomized studies and selection bias.
- Ignores recent large-scale studies with long-term follow-up.
- Misrepresents recurrence rates by citing outdated studies (e.g., Cognetta 2012).

IGSRT as a Distinct, Advanced Technology

- LCD fails to distinguish IGSRT from older SRT.
- Most cited studies predate IGSRT (pre-2013).
- IGSRT studies show >99% FFR at 2, 4, and 6 years using post-2016 technology.

Clinical Advantages of IGSRT

- Real-time ultrasound enables precise targeting and dose adjustment.
- Reduces side effects and improves outcomes.
- Demonstrated efficacy across all demographics and tumor characteristics.

Access and Utilization

- IGSRT is now the most widely used radiation therapy for NMSC.
- Over 170,000 lesions treated.
- LCD's "qualified physician" clause may restrict dermatology practice reimbursement.

Guideline Limitations

- LCD relies on outdated guidelines (e.g., 2020 ASTRO) that don't reflect recent IGSRT data.
- Calls for decisions based on current peer-reviewed literature.

Consistent Efficacy Across Patient Groups

- Studies show no difference in outcomes by:
    - Age, sex, tumor location, socioeconomic status, or comorbidities.

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- 99% FFR across all stages and subtypes (BCC, SCC, SCCIS).

Recent Supporting Publications (2023–2025)

- 11 peer-reviewed studies cited, including:
    - McClure et al., Yu et al., Agha et al., Farberg et al., Ma et al.
    - Demonstrate superior outcomes and broad applicability of IGSRT.

Rob Burnside

- What is Xoft/Elekta? What is EBT?
- Nomenclature clarification
- What is HDR-EBT? How different from both SRT and electronic brachytherapy?
    - Physician role and State regulations
- Importance of high doses and superiority of HDR-EBT to SRT
- Comparison of HDR-EBT peer reviewed literature to SRT
- Patient Benefit – Surgery vs. non-surgery
- Patient Access to appropriate care

Dr. J Cheng

Why Electronic Brachytherapy (EBx) Must Remain a Covered Option for Non-Melanoma Skin Cancer (NMSC)

Patient-Centered Choice and Equity

- EBx is vital for elderly and comorbid patients who can't tolerate surgery or prolonged therapy.
- Offers superior cosmetic and functional outcomes for sensitive areas (e.g., nose, eyelids).
- Removing EBx reduces access and limits physician and patient autonomy.

Clinical Appropriateness and Treatment Efficiency

- EBx typically requires only **8–10 treatment fractions**, reducing patient burden.

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- Proven to deliver excellent **local control and cosmetic results**, especially for early-stage BCC and SCC.

Safeguarding Medicare Against Abuse

- Concerns raised about **SRT overutilization** (20–30+ fractions) by non-oncology-trained providers.
- EBx is **protocol-driven**, with shorter courses that reduce overbilling risks.
- Eliminating EBx while allowing high-fraction SRT is contradictory and counterproductive.

Cost-Effectiveness and Healthcare Stewardship

- Fewer fractions mean **lower overall treatment costs**.
- EBx is often more economical than extended SRT or Mohs surgery with reconstruction.
- Advocates for **targeted oversight** rather than eliminating a cost-effective modality.

Policy Alignment with CMS Goals

- Supports:
    - **Value-based care**.
    - **Reduced unnecessary utilization**.
    - **Innovation in outpatient cancer care**.

Closing Appeal

- Urges CMS not to eliminate EBx due to broader market concerns.
- Recommends **refined coverage criteria and oversight** instead of restricting access.
- Emphasizes EBx as a **clinically appropriate, evidence-based** treatment option for Medicare beneficiaries.

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