

**Innovation for High-Value Radiotherapy: An Informal Request for Information on Radiation Oncology
Model Clinical Data Elements (CDEs) from the Center for Medicare and Medicaid Innovation**

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Overview

The Center for Medicare & Medicaid Services' (CMS') Innovation Center finalized the Radiation Oncology (RO) Model to test whether prospective episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPD), and freestanding radiation therapy centers for radiotherapy (RT) episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care. The RO Model policies and regulations are included in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule. The final rule (CMS 5527-F) can be downloaded from the Radiation Oncology Model website at <https://innovation.cms.gov/initiatives/radiation-oncology-model/>.

In an effort to shepherd the development of new outcome measures in radiation oncology, explore opportunities to inform pricing for episodes in the RO Model, and inform monitoring of care quality during the RO Model, the Innovation Center will collect clinical data elements (CDEs) from RO participants beginning in Performance Year (PY) 1 (January 1, 2021 -December 31, 2021) as described in Section III. C. 8.e. of the Final Rule.

The Innovation Center aims to minimize data collection burden for RO participants to the extent possible, consistent with the CMS Administrator's Patients over Paperwork initiative that aims to reduce unnecessary burden.

We are laying out draft CDEs for public comment. At this time, CMMI will only consider removal of CDEs for Performance Year 1. See the below bulleted list.

Solicitation of Comments

The Innovation Center solicits comment from the general public on the suggested CDEs listed in the below bulleted list by October 19, 2020, which is 31 days after its posting. Written feedback can be sent to RadiationTherapy@cms.hhs.gov until the close of the feedback period.

The Innovation Center would appreciate comments as they relate to the goals described above, including each element's potential use in developing new outcome measures and informing pricing and monitoring, while at the same time minimizing collection burden. At this time, CMMI is only considering removal of CDEs for Performance Year 1.

Additional Comments

The Innovation Center, at their discretion, may opt to conduct individual or group stakeholder meetings during the finalization of the CDEs. Individuals or entities submitting comments may indicate their interest in participation in these meetings, should they occur.

Draft Clinical Data Element (CDE) Listing for the RO Model

The Innovation Center plans to collect CDEs for five cancer types: prostate, breast, lung, bone metastasis, and brain metastasis. Draft CDEs are listed by cancer type below.

Prostate Cancer

- Beneficiary ID
- Total Dose Delivered
- Number of Fractions Delivered
- Eastern Cooperative Oncology Group (ECOG)¹ Performance Status
- American Joint Committee on Cancer (AJCC)² Stage (T, N, M)
- Treatment Intent (palliative or curative)
- International Society of Urological Pathologists (ISUP)³ Grade Group
- Treatment Timing (initial treatment or post-prostatectomy)
- Prostate-Specific Antigen (PSA) Level
- Size of the prostate
- Treatment of pelvic lymph nodes (yes or no)
- Dose Constraints to Target
- Dose Constraints to Rectum
- Dose Constraints to Bladder

Breast Cancer

- Beneficiary ID
- Total Dose Delivered
- Number of Fractions Delivered
- ECOG Performance Status
- AJCC Stage (T, N, M)
- Treatment Intent (palliative or curative)
- Histology (Ductal carcinoma in situ, infiltrating ductal carcinoma, infiltrating lobular carcinoma, mixed ductal/lobular carcinoma, other)
- Laterality (left, right or bilateral)
- Treatment Plan (whole breast, post-mastectomy, partial breast 1-per day, partial breast 2-per day, palliation of local occurrence)
- Mammary Nodes Treated (internal mammary, supraclavicular, and axillary)
- Dose Constraints to Target
- Dose Constraints to Heart
- Dose Constraints to Ipsilateral Lung

Lung Cancer

- Beneficiary ID

¹ <https://ecog-acrin.org/resources/ecog-performance-status>

² <https://cancerstaging.org/>

³ <https://isupweb.org/>

- Total Dose Delivered
- Number of Fractions Delivered
- ECOG Performance Status
- AJCC Stage (T, N, M)
- Treatment Intent (palliative or curative)
- Histology (small cell, non-small cell, or pleural neoplasm)
- For Small Cell, Prophylactic Cranial Irradiation (PCI) (yes or no)
- For Small Cell, Treatment to Primary Site (yes or no)
- For Non-Small Cell, Positive Margin Status (yes or no or N/A)
- For Non-Small Cell, Post-Op Residual Tumor other than positive margins (yes or no)
- For Non-Small Cell, Extracapsular Extension Present (yes or no)
- Dose Constraints to Target
- Dose Constraints to Non-Target Lung (Lung Minus CTV)
- Dose Constraints to Heart

Bone Metastasis Cancer

- Beneficiary ID
- Total Dose Delivered
- Number of Fractions Delivered
- ECOG Performance Status
- Number of Fields Treated
- Prior Radiation to an Overlapping Area (yes or no)
- Bone Lesions in Spine Being Treated (yes or no)

Brain Metastasis Cancer

- Beneficiary ID
- Total Dose Delivered
- Number of Fractions Delivered
- ECOG Performance Status
- Treatment Type (whole brain or stereotactic)
- Prior Treatment to Brain (yes or no)
- Number of Active Lesions at the Start of the Episode