Cancer Center CTO Routine Care Labs, Imaging, & Provider Visits at Locations More Convenient for Trial Participants

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Background

Our center wanted to increase accessibility of clinical trials by decentralizing services to community locations more convenient for patients. Our goal was to establish joint guidance to accommodate routine care labs, imaging, and provider visits at alternate locations. We defined "alternate locations" as locations not included in the IRB submission, Form FDA 1572, or our Clinical Trial Management System (CTMS) study sites tab. We defined "routine care" as a service billable to patient/insurance per Medicare Coverage Analysis (MCA) determination.

Goals

- To increase access to clinical trials by allowing routine care labs, imaging, and visits with local health care providers (HCPs) to occur at locations more convenient for patients
- To provide a road map to study teams regarding when and how to compliantly support routine care labs, imaging, and provider visits at alternate locations
- To facilitate compliant billing for routine care in the context of a qualifying clinical trial per Medicare requirements

Solutions and Methods

A workgroup comprised of staff from CTO, local IRB, hospital research compliance, and provider research billing was formed to establish joint guidance to accommodate routine care labs, imaging, and provider visits at alternate locations.

We determined that alternate locations would be allowable for these services if they met **all** of the following criteria:

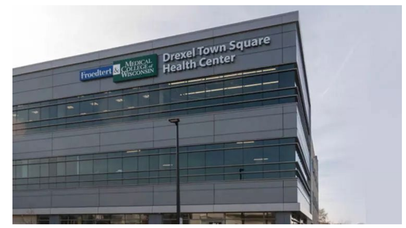
- Billable to patient/insurance per the approved MCA
- Protocol/Sponsor/Central Vendor allows (no site selection and/or credentialing required)
- Requires no study-specific knowledge, support, notification, or guidance to clinical staff to conduct (i.e., lab/imaging/visit would be ordered/performed following the same clinical standard outside of research)

If routine care labs, imaging, or provider visits are proposed for an alternate location, coordinator to:

- Confirm all visits under consideration meet the above criteria
- Ensure proper medical release (HIPAA Authorization) is in place to obtain records in a timely and compliant manner
- Ensure that reports from local HCPs include the name of the local HCP and the date when activities were performed
- Work with regulatory to add site to the Form FDA 1572 as applicable
- Notify patient billing team(s) as required to facilitate billing modifier for routine care in the context of a qualifying clinical trial

Outcomes

Institutional guidance was finalized in late 2023 referencing draft FDA Guidance on Conducting Clinical Trials with Decentralized Elements. Implementation, including training for staff and investigators, took place in early 2024. The FDA finalized its guidance in September 2024 and included changes such as eliminating the need to maintain a log of local HCPs performing trial-related activities.



Lessons Learned and Future Directions

We continue to look for opportunities to compliantly revise and expand decentralized services within the framework allowed by protocols, current regulations, and FDA guidance to better serve patients in our catchment area. Possible areas for expansion include routine chemo/RT, biopsies, and other trial-related activities not requiring specific instructions from the protocol.

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