Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Work in Progress

The Financial and Operational Challenges of CAR T Therapy Expansion

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1. Background

Cellular therapies (CT), including chimeric antigen receptor T-cell (CAR T) therapy, are complex, personalized, high-risk treatments, which require a multidisciplinary team of highly skilled medical professionals to manage potentially life-threatening toxicities and required intensive in-patient and out-patient monitoring. CAR T revolutionized treatment of certain leukemias and lymphomas. Clinical trials are expanding the use of CAR T in solid tumors, including in brain, pancreatic, lung and ovarian cancers and further into non-oncology specialties, targeting autoimmune, inflammatory and infectious diseases. The Lombardi Comprehensive Cancer Center (LCCC), is harnessing the cross-consortium expertise of our oncology providers, research administrators and budget analysts to significantly increase our CT clinical research portfolio, including investigator-initiated trials (IITs). Importantly, CT products and patient care during treatment are costly and insurance reimbursement is inadequate. Therefore, the rapid expansion of the CT clinical trials program at LCCC created important financial and operational considerations, including revenue cycle implications and reimbursement challenges, versus non-CT clinical trials, especially with IITs.

2. Goals

- Institute a financial framework to ensure the financial viability of the CT research program
- Establish an operational blueprint to ensure clear delineation of responsibilities between LCCC cell therapy team, and non-oncology teams entering the CT space
- Broaden CT clinical trials program to include IITs

3. Solutions and Methods

- Adapt Study Start-up Agreement for non-CT clinical trials to include modified CT costs
- Adopt a strategic approach to budgeting (inpatient versus outpatient, Diagnosis-Related Group (DRG) Reimbursement models versus Current Procedural Terminology (CPT) Codes, modeling Start-up and annual fees based on real salary data).
    - Early collaboration with the cell therapy team to guide financial coverage
    - Plans for navigating interdepartmental needs (Cell Therapy Manufacturing Facility, Bone Marrow Collection Program, Radiology, Pharmacy, Non-Oncology Departments)
- Outline agreements for study lifecycle financial management (particularly with Non-Oncology Departments)
- Adjust budget model for CT-based IITs, leveraging clear guidance from Centers for Medicare & Medicaid Services (CMS) on CAR T billing for clinical trials and ensuring financial viability on balance with advancing Lombardi science

4. Outcomes

- Developed sufficient start-up and annual Cell Therapy to support specialized staff salaries

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- Per patient budgets are properly coded and reimbursed
    - No split billing during inpatient periods
    - Adequate reimbursement for Oncology studies and provides a basis to negotiate with non-Oncology studies.
- Robust oncology CT portfolio, including multiple IITs in start-up and quickly growing non-oncology portfolio

5. Lessons Learned and Future Directions

- Further customize Start-up/Reimbursement amounts to account for CT studies that are lower risk
- Educate the research and clinical teams regarding back-end billing on CAR T Clinical Trial Reimbursement policy (e.g., MS-DRG-018, NCD 110.24) and educate Principal Investigators (PIs) on CAR T billing policy