The Financial and Operational Challenges of CAR-T Therapy Expansion: Building a Tiered, Transparent Framework for Cellular Therapy Trial Budgets

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Background

Lombardi Comprehensive Cancer Center (LCCC) is leveraging cross-consortium expertise to grow its CT portfolio, including investigator-initiated trials (IITs) and provide support to the expanding non-oncology clinical trials portfolio. However, CT products and patient care are costly, and insurance reimbursement is complex. Rapid CT trial expansion has created significant revenue-cycle and reimbursement challenges compared to standard interventional studies.

Goals

- **Financial viability:** Build a framework that ensures the CT research program is financially sustainable
- **Operational clarity:** Establish a blueprint that clearly delineates responsibilities between the Lombardi cell-therapy team and non-oncology teams entering the CT space
- **Broaden access:** Expand the CT trial portfolio to include IITs and non-oncology indications
- **Transparency:** Publish a standardized, tiered fee schedule that sponsors can review prior to contract negotiation

MS-DRG-018: Inpatient Reimbursement for CAR-T

MS-DRG 018

Federal inpatient payment driver for CAR-T therapies, modified for clinical trials. % of payment (16% in 2026) is provided since sponsor covers manufacturing.

- **Single bundled payment –** covers the entire inpatient stay: no split billing between routine costs and study-specific charges.
- **Routine Care:** if the Inpatient stay can be considered routine care, the Medicare Coverage Analysis must consider all billable events during the inpatient stay as Routine Care.
- **Non-oncology or Non-covered inpatient stays:** provides a clear benchmark for what costs should be recuperated (Usually $60k - $75k per use of MS-DRG-018 on a clinical trial.

THE NEGOTIATION CHALLENGE

"STICKER SHOCK"

High start-up + monthly maintenance fees can reach 5-figures or more, before a single patient is enrolled.

- **Cost surprises mid-negotiation** stall contracts
- **Non-oncology sponsors** unfamiliar with CT infrastructure costs and DRG-based inpatient reimbursement

Solutions & Methods

- **Tiered fee schedule:** Three risk-stratified tiers (Lower / Moderate / High) capturing the full range of CT studies — not just CAR-T with lymphodepletion + inpatient admission
- **Study Start-Up Agreement (SSUA):** Adapted from non-CT studies; secures sponsor agreement to non-negotiable activation fees before formal budget negotiations begin
- **Strategic budgeting:** Inpatient vs. outpatient logic, MS-DRG vs. CPT reimbursement modeling, start-up and annual fees grounded in real salary and infrastructure data
- **Early cell-therapy team engagement:** Coverage analysis and feasibility input from the cell-therapy core before CTA drafting
- **Interdepartmental playbook:** Defined hand-offs across CTMF, BMCP, Radiology, Pharmacy, and non-oncology departments
- **Lifecycle financial management:** Start-up, monthly maintenance, and close-out are negotiated together — not sequentially
- **IIT-specific model:** Adjusted budget templates leveraging CMS guidance on CAR-T billing for clinical trials

LOMBARDI CTO TIERED RISK MODEL

*All **CT** trials require heightened oversight. Tiers reflect operational acuity — not just CAR-T with inpatient admission.*

TIER	RISK PROFILE
TIER 1	**LOWER RISK** Managed under Cell Therapy Program; increased observation, generally no inpatient admission.
TIER 2	**MODERATE RISK** May require inpatient management at PI discretion; meaningful potential for CRS/ICANS.
TIER 3	**HIGH RISK** Generally inpatient; 24/7 on-call readiness; specialized cell-processing workflows.

TRANSPARENCY + THE SSUA

The Administrative fee schedule and Study Start-Up Agreement (SSUA) places every non-negotiable cost in front of the sponsor before formal negotiation begins.

- **Shareable Administrative Fee Schedules w/ Justification:** Provided to the sponsor upfront, signed, and version-controlled.
- **SSUA signed pre-CDA / pre-CTA:** locks in tier classification and non-negotiable start-up totals.
- **Eliminates back-and-forth** on fees that institutional policy will not move on (start-up, IRB, FACT/biosafety).
- **Frees negotiation bandwidth** for the items that matter: per-patient costs, IP supply, sponsor-specific procedures.
- **Builds sponsor trust** through visible, defensible cost recovery rather than line-by-line surprises.

3-YEAR COST RECUEPRATION MODEL

- ✓ Aim to cover research personnel costs dedicated to CT portfolio
- ✓ Combination of Start-up costs, Close-Out Costs, Recurring Fees
- ✓ Lombardi model began in Q1 2026

Outcomes

- **Sustainable start-up + annual fees** supporting specialized CT staff salaries.
- **Per-patient budgets** properly coded and reimbursed; no split billing during inpatient periods.
- **Adequate reimbursement** for oncology CT studies; provides a defensible baseline for non-oncology negotiations.
- **Recuperated 23% of 3-year goal** within first 6 months

Lessons Learned & Future Directions

1. Educate research teams on the operational burdens of CT trials, back-end CAR-T billing (*e.g.*, MS-DRG-018, NCD 110.24) and billing policies well before sponsor engagement.
2. Build sponsor-facing one-pagers explaining tier rationale to shorten negotiation cycles.
3. Refresh the 3-year recuperation model quarterly; tie tier reassignments to actual operational burden data.

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