

BACKGROUND

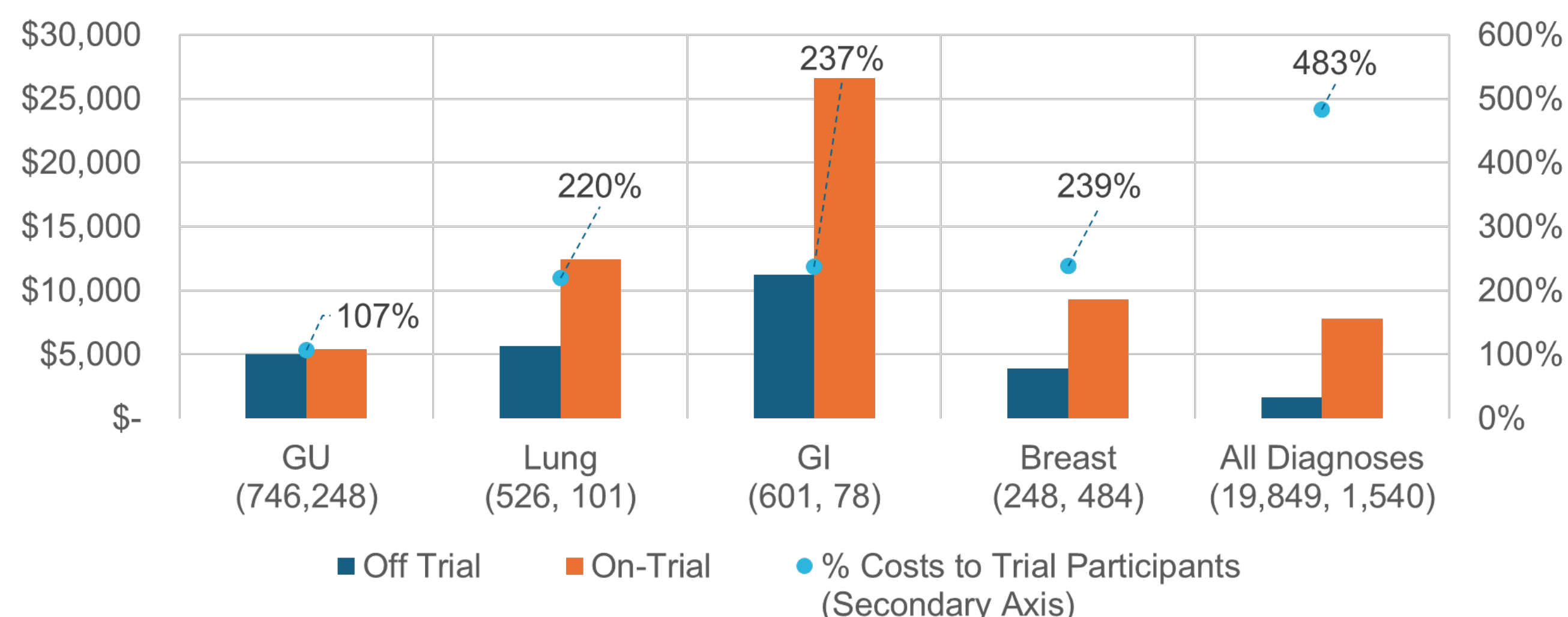
The National Coverage Decision enacted in 2000, changed the clinical trials finance landscape, creating a path for Centers for Medicare & Medicaid Services beneficiaries to participate in qualifying clinical trials. NCD310.1 has enabled health care providers to seek reimbursement for routine costs associated with qualifying clinical trials (QCTs). Determination of what constitutes a routine cost in a QCT, and the downstream monitoring of financial activity associated with clinical trial and participant activity, is mired in the nuances of navigating specialty guidelines, Medicare coverage limitations, and historical billing precedent. Without careful consideration of third-party payer benefits, the clinical trial participant is caught in a maze of complex hospital billing, unaligned clinical trials industry sponsorship, and federal regulations – ultimately bearing a far-greater financial burden for their contributions to advancing medicine.

GOALS

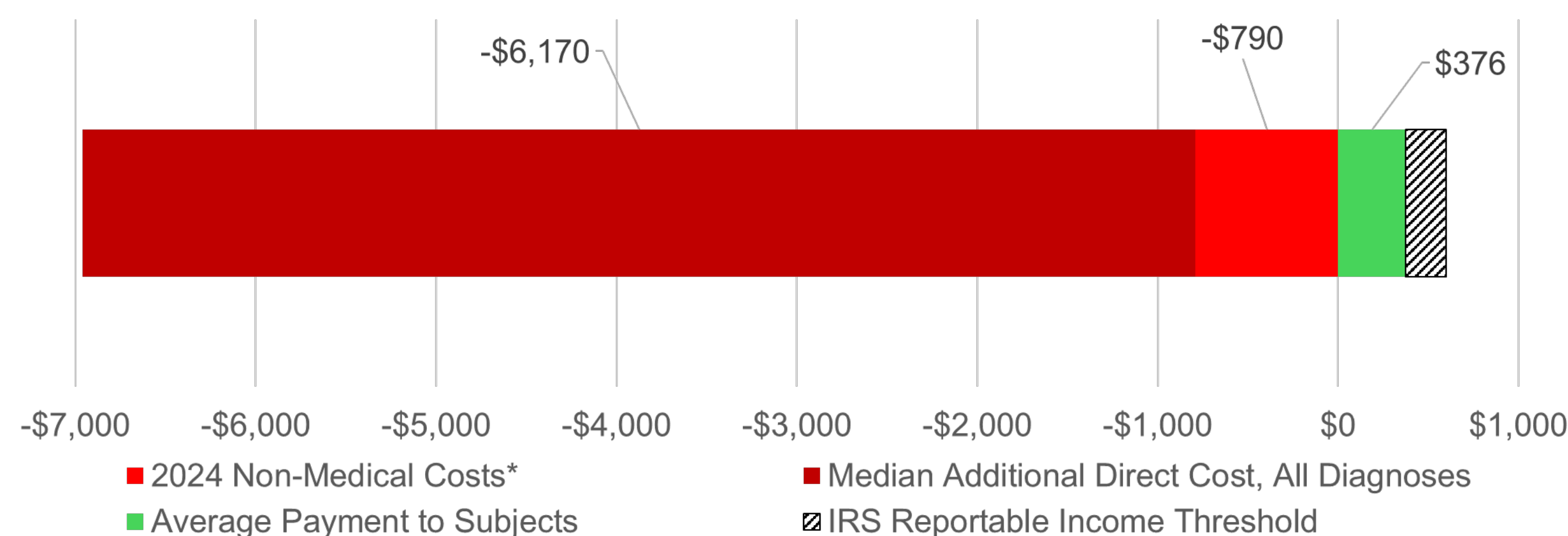
- Evaluate out-of-pocket costs associated with clinical trials participation at one site from an NCI-Designated Cancer Consortium amongst straight-pay Medicare clinical trial participants versus non-participants
- Report updated non-medical costs associated with clinical trial participation
- Derive total out-of-pocket financial impact to treatment trial participants
- Frame additional out-of-pocket cost and reporting burden to current participant and health system IRS reporting requirements
- Scan current legislative reform initiatives and inform sensible federal policy change

SOLUTIONS & METHODS

Estimated Median Direct Out-of-Pocket Cost for Outpatient Medicare Charges One Year Post Diagnosis, Enrolled in Treatment Trial vs: Not Enrolled



Estimated Total Additional Out-of-Pocket Costs One Year Post Diagnosis to Clinical Trial Participants versus Average Annual Payments to Participants



*Previously published¹ average non-medical out-of-pocket cost updated to 2024 dollars associated with travel and lodging for clinical trials participants

OUTCOMES

- Medicare subjects enrolled in clinical trials had a higher out-of-pocket payment burden nearly five times greater than their counterparts
- Information systems infrastructure/support for tracking subject payments added more than \$108K in direct institutional cost in the first year of system implementation
- Subjects have an average additional \$6,584 net out-of-pocket burden (estimated)
- Average subject compensation qualifying for IRS-1099 reporting/issuance does not offset the median additional out-of-pocket costs associated with clinical trial participation.
- Taxing compensation to oncology clinical trials participants mandates safe harbors from IRS reporting and immediate policy reform

LESSONS LEARNED/FUTURE DIRECTION

- The legal framework around supporting trial participants financially provides disincentives for sponsors to provide support and can penalize patients who receive support
- H.R. 7090/7418 Harley Jacobsen Clinical Trial Participant Income Exemption Act would make any compensation received by cancer clinical trial participants exempt from taxation and therefore also not count toward eligibility for Medicaid, CHIP, or marketplace subsidies

CONTACT & REFERENCES

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¹Nipp RD, Powell E, Chabner B, Moy B. Recognizing the Financial Burden of Cancer Patients in Clinical Trials. *Oncologist*. 2015;20(6):572-575. doi:10.1634/theoncologist.2015-0068