Budget Impact of a PreTRM®-Guided Preventive Bundle for Preterm Birth in Low-Risk Pregnancies: A Microsimulation Study Using PRIME Trial Data

P. KEARNEY¹, A. BHOLLAH¹, and E. STANEK²

¹Sera Prognostics, Inc., Salt Lake City, UT, USA, ²Carelon Research, Wilmington, DE, USA

INTRODUCTION

Preterm birth remains a leading cause of neonatal morbidity and healthcare expenditure, even among pregnancies considered low risk.

Early identification and targeted intervention strategies offer a promising avenue to reduce adverse outcomes and associated costs.

This study estimated the 3-year budget impact of a PreTRM® Test-guided intervention bundle aimed at reducing neonatal intensive care unit (NICU) stays and first-year-of-life costs using a microsimulation model based on real-world data.

OBJECTIVE

To estimate the 3-year budget impact of a PreTRM® Testguided preventive intervention bundle, applied to low-risk singleton pregnancies stratified for preterm birth risk.

- Daily low-dose aspirin
- Daily vaginal progesterone
- Weekly care management (from 24 weeks' gestation until delivery or 36 weeks)

The analysis used an individuallevel microsimulation model that accounted for patient heterogeneity in a low-risk population.

*Maximum cost from bundle initiation to full-term delivery.

METHOD

Develop a microsimulation model from a mixed-payer perspective using individual-level data from the PRIME randomized controlled trial.

- Simulate the 1M commercial health plan members representative of the target population over a 3-year time horizon, incorporating variability in demographics, obstetric outcomes, treatment adherence, and clinical effectiveness.
- 2024 costs included standard pregnancy care, direct and indirect costs of the intervention bundle, NICU length of stay, and first-year-of-life healthcare utilization.
- NICU and postnatal costs were derived from a claimsbased cohort of 62,093 pregnancies in the HealthCare Integrated Research Database (2016, Carelon Research).
- Key model inputs such as number needed to screen to reduce a NICU day and gestational age shifts were based on outcomes from the PRIME trial. (ClinicalTrials.gov #NCT04301518; Iriye BK et al. Pregnancy 2025;1:e12035)

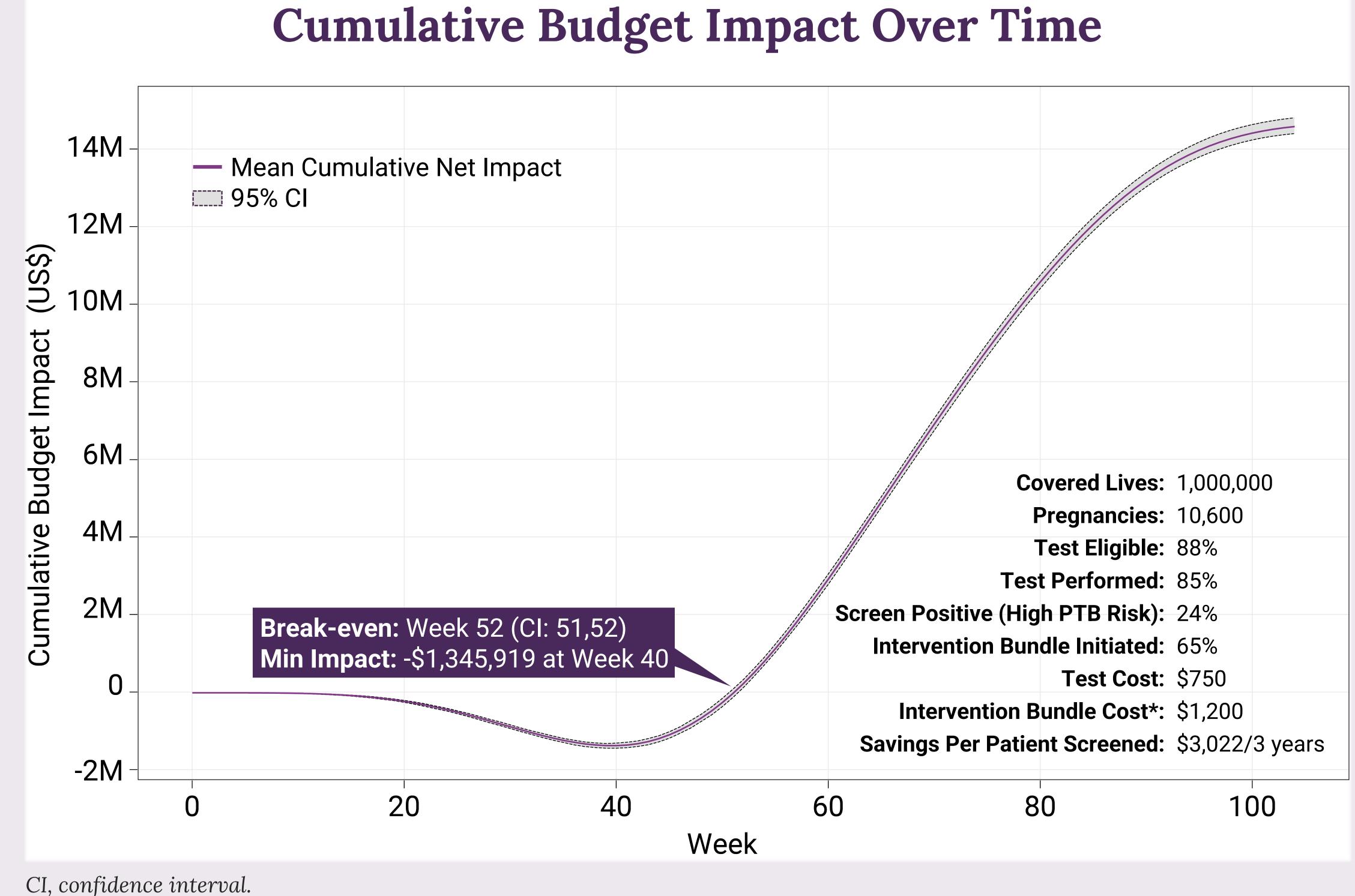
RESULTS

Relative to standard care, the PreTRM-guided intervention bundle:

- yielded a net savings of \$2.1 per member per month by year 3 (95% CI, \$2.1-2.2)
- achieved break-even at 52 weeks (95% CI, 51-52 weeks) and
- required a maximum investment of \$6.5M (95% CI, \$6.47-6.57M), which occurred by week 60.

The total net savings at 3 years for 1M covered lives was \$15M.

Sensitivity analyses identified NICU day cost, first year of life healthcare cost and test adoption and intervention compliance rate (these were bundled together) as the most influential model parameters.



CONCLUSIONS

This microsimulation provides robust budget impact estimates for a PreTRM-guided strategy, demonstrating the potential for clinically targeted, cost-saving interventions in a low-risk pregnancy population.

CONTACT

Abdool Bhollah abhollah@sera.com

Paul Kearney pkearney@sera.com





