Date: [Insert Date]
To: Medical Policy Department
State of _____/Health Plan _____

Subject: Request for Coverage

Dear Decision Maker

I respectfully request consideration of coverage for the **PreTRM® Test (0247U PLA)**, a blood-based proteomic assay that predicts risk of spontaneous preterm birth in asymptomatic, singleton pregnancies. This request is based on **new, high-quality evidence** from the recently published **PRIME randomized controlled trial**[1], which demonstrates significant improvements in neonatal outcomes and reductions in healthcare utilization. The results of the PRIME study are in alignment with previous PreTRM studies evaluating the ability of the test to identify risk and the impact of the intervention bundle to improve outcomes for families. Based on the evidence the PreTRM Test can positively impact health outcomes for (insert State)'s expectant mothers and babies.

Why Coverage Matters

Preterm birth remains one of the most pressing challenges in maternal and neonatal health:

- **Prevalence:** 1 in 10 U.S. babies is born prematurely (10.4% in 2024).[2]
- **Impact:** Preterm birth complications are a **leading cause of death** in children younger than 5 years and remain one of the **most critical causes of neonatal mortality.**[3]
- **Unpredictability:** Nearly **50% of preterm births occur in women with no known risk factors**[4]**,** leaving clinicians without tools to intervene early.
- **Health Equity:** Black women experience a **14.7% preterm birth rate**[2], and Medicaid covers **41% of U.S. births**[5]—a population disproportionately affected by prematurity.

These statistics underscore the urgent need for **accurate, early risk identification** to guide personalized and proactive care.

About the PreTRM® Test

The PreTRM Test is performed at $18^{0/7}$–$20^{6/7}$ weeks of gestation and provides a biologically based risk assessment for spontaneous preterm birth and its complications, before symptoms are present. This allows clinicians to **implement evidence-based interventions earlier in pregnancy** which improve outcomes for mothers and babies. Currently accepted predictors for preterm birth consist of cervical length screening, which identifies 8% of those at risk, and a history of a prior preterm birth, which can identify 11% of at-risk women. The PreTRM Test has been validated to identify 77%[6] mothers at risk for preterm birth.

Multiple studies confirm that PreTRM® risk stratification enables targeted interventions that **change the trajectory of care**, leading to reduced costly complications, and decrease healthcare resources through delivering healthier babies.

Improvement in outcomes seen in peer reviewed literature of PreTRM testing is consistent across various study designs and collectively indicates positive impact on maternal and neonatal outcomes.

Sera has preformed 10+ studies on over 23,000+ patients assessing PreTRM capabilities and impact.
Specifically, the PRIME[1] study (5000+ patient, 19 site Randomized Controlled Trial) showed decreased NICU admissions, reduction in the earliest preterm births (<32 and <35 weeks), and improved neonatal health outcomes, including:

- 20% fewer NICU admissions than routine care
- 20% reduction in composite neonatal morbidity/mortality
- 56% reduction in PTB <32 weeks
- 32% reduction in PTB <35 weeks

Based on PRIME[1] trial results, the Number Needed to Screen (NNS) for the PreTRM Test is

- 38.5 to prevent one NICU admission
- 4.2 to prevent one NICU day
- This performance is significantly better than guideline-supported cervical length screening, which has an NNS of 150 to prevent one NICU admission.

Request for Coverage- Based on new clinical evidence building on a strong foundation of 12 peer-reviewed studies, and the unmet need for risk identification in expectant mothers before symptoms begin and when action can lead to the best impact, PreTRM should be covered for women managed by (insert state Medicaid agency)/(insert health plan).

Sincerely,

(Insert Provider Name, Contact Information and NPI#)

COLL-279 PreTRM PTB Risk Stratification Dossier__blank_copy_id_13417208.pdf

Read our PreTRM Dossier

Citations

1. PRIME - RCT - https://doi.org/10.1002/pmf2.70202 Iriye BK, O'Brien JM, Ennen CS, et al. Neonatal impact of maternal biomarker screening for risk of preterm birth with targeted interventions (PRIME): A multicenter, randomized, controlled trial. Pregnancy 2026;2(1):e70202.
2. Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final Data for 2023. Natl Vital Stat Rep 2025(1):1. (In eng). DOI: 10.15620/cdc/175204.
3. Cao G, Liu J, Liu M. Global, Regional, and National Incidence and Mortality of Neonatal Preterm Birth, 1990-2019. JAMA Pediatrics 2022;176(8):787–796. DOI: 10.1001/jamapediatrics.2022.1622.
4. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics. Prediction and Prevention of Spontaneous Preterm Birth: ACOG Practice Bulletin, Number 234. Obstet Gynecol 2021;138(2):e65–e90. DOI: 10.1097/AOG.0000000000004479.

5. Centers for Medicare & Medicaid Services. 2024 Medicaid & CHIP Beneficiaries at a Glance: Maternal Health. (https://www.medicaid.gov/medicaid/benefits/downloads/2024-maternal-health-at-a-glance.pdf). Accessed December 31, 2025.
6. .Polpitiya A, Cox C, Butler H, et al. Integrating clinical factors and parity-specific models with molecular biomarkers to better predict the risk of preterm birth in asymptomatic women. medRxiv 2026:2026.03.13.26348357. DOI: 10.64898/2026.03.13.26348357