NL Health Services

Memorandum

To: Prenatal Care Providers

From: Department of Pathology and Laboratory Medicine and Provincial Medical Genetics Program, Medicine Program

Date: March 5th, 2024

Re: New Funding Available - Non-Invasive Prenatal Screening (NIPT) for "High-Risk" Patients

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Government funding is now available for non-invasive prenatal screening (NIPT) for patients meeting certain high-risk eligibility criteria. Funded NIPT for patients meeting these criteria can now be requested by a variety of primary care providers including (but not limited to) obstetricians, family doctors, nurse practitioners, and midwives. Maternal serum screening (MSS) should **not** be ordered for a patient who has had NIPT completed already in that pregnancy.

Patients meeting these higher risk criteria include:

- Maternal age of 37 or greater at the time of delivery (in the case of in vitro fertilization, maternal age is dictated by the maternal age at egg retrieval)
- MSS screen-positive result for trisomy 21 or trisomy 18 (gestation confirmed by ultrasound).
    - Patients with an MSS screen-positive for open spina bifida do **not** qualify for funded NIPT.
- History of aneuploidy in a previous pregnancy
- Twin pregnancy with demonstration of fetal cardiac activity in both

Patients do **not** require a referral to the Provincial Medical Genetics Program to access NIPT. Patients should continue to be referred to the Provincial Medical Genetics Program prenatally for the following indications:

- Personal or family history of a known genetic condition
- Fetal anomalies or soft markers identified on prenatal ultrasound
- Screen-positive or inconclusive NIPT results
- Positive maternal serum screening result or history of aneuploidy in a previous pregnancy if the patient wishes to proceed with invasive testing, such as chorionic villus sampling or amniocentesis

Ordering Instructions – High-Risk, Funded NIPT

High-risk NIPT is available using "Harmony", provided by the laboratory at Dynacare. The requisition is available at https://www.gov.nl.ca/labformulary/forms/ and a copy is attached for your reference. Please

ensure the requisition is completed in full, including the patient's EDC, height, weight, and screening preferences (including if the patient wishes to screen for the fetal sex and/or sex chromosome aneuploidies). On the eligibility form, clearly select which of the high-risk criteria apply to your patient under the section marked "Category 1". Indications under "Category 2" are restricted to ordering by Medical Genetics and Maternal Fetal Medicine providers.

Harmony NIPT must be collected in kits provided by the vendor, Dynacare. Kits should **not** be ordered to the patient's personal address. Initially, Harmony NIPT kits will be available at major blood collection centres across the province and more broadly in the coming weeks. For concerns about accessing NIPT kits, please contact Dynacare directly at 1-888-988-1888.

Average-Risk, Patient-Pay NIPT

Patients not meeting the above criteria can still access NIPT. The associated cost of NIPT for patients at average risk must be paid by the patient. This can be arranged by the prenatal care provider. Information is attached outlining the available options for patient-pay NIPT. It is noted that the laboratory at "Invitae" is discontinuing NIPT. New NIPT orders will not be accepted by Invitae as of March 8th, 2024. Samples received by Invitae's laboratory after March 16th, 2024, will not be processed.

Of note, all pregnant patients in Newfoundland and Labrador, regardless of their risk, continue to have access to publically-funded MSS.

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