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DATE: February 4, 2021

TO: Ordering physicians
Genetic clinics

FROM: Neeta Sarta
Acting Director
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SUBJECT: Update Regarding the Ministry of Health's Out-of-Country/Out-of-Province
Prior Approval Program for Laboratory Testing and Whole Exome Sequencing

Effective April 1, 2021, Whole Exome Sequencing (WES) for rare disease diagnostics in children and adults will be available in Ontario on a routine test turnaround time ("routine WES").

Pursuant to sections 28.0.2 and 28.5 of Regulation 552 under the Health Insurance Act, laboratory testing that is performed in Ontario does not meet the requirements for insured Out-of-Country (OOC) or Out-of-Province (OOP) laboratory testing. Therefore, after April 1, 2021, the Ministry of Health (ministry) OOC/OOP Prior Approval (PA) Program for Laboratory Testing will no longer accept applications requesting routine WES for rare disease diagnostics.

Applications for routine WES received by the OOC/OOP PA Program prior to April 1, 2021 will be processed as requested. Applications received on or after this date will not be processed and ordering physicians will be redirected to the testing available in Ontario.

Applications for WES ordered for other indications should continue to be submitted to the OOC/OOP PA Program for Laboratory Testing. Examples of such indications include:

1. Fetal cases in an on-going pregnancy, or
2. Medically urgent cases for which expedited results (< 4 weeks) are required and expected to immediately alter management.

Routine Turnaround Time Whole Exome Sequencing for Rare Disease Diagnostics

Effective April 1, 2021, patients who meet the ministry's eligibility criteria can receive routine WES in Ontario through a genome-wide sequencing pilot project being conducted collaboratively at the Genome Diagnostics Laboratory at The Hospital for Sick Children (SickKids) and the Genetics Diagnostic Laboratory at CHEO, a pediatric hospital and research centre in Ottawa.

For all genome-wide sequencing performed in Ontario, ordering physicians will be required to participate in data collection to support ongoing oversight and project outcomes evaluation. The Ontario-based data will be used to help guide ministry decisions on establishing this service in Ontario long-term.

More information about the testing at SickKids and CHEO, including patient eligibility criteria, requisitions, sample requirements, and data collection requirements can be found here www.gsontario.ca.

For questions related to the Ministry of Health's OOC/OOP PA Program for Laboratory Testing, please contact Outofcountrylabsgenetics@ontario.ca.

Sincerely,



Neeta Sarta