Signatera™
Residual disease test (MRD)

Date: July 30, 2020
Subject: Natera - GI Cancer Expanded Access Program

Dear Colleagues,

With the outbreak of COVID-19, many cancer patients and oncologists will interrupt their standard surveillance schedules, or may wish to avoid or delay chemotherapy because it can significantly weaken the immune system.

To support you and your patients at this challenging time, Natera is announcing its **GI Cancer Expanded Access Program,** making Signatera MRD testing remotely available for patients with any type of GI cancer who are candidates for reducing chemotherapy or are at risk of delayed surveillance visits. Studies have shown that patients who test MRD-negative with Signatera are at significantly reduced risk of relapse, and based on clinical assessment may be eligible for treatment de-escalation and fewer scans.[1-4]

Through the GI Cancer Expanded Access Program, effective immediately:

- Physicians can order Signatera and receive test results virtually through Natera's online portal
- Natera will send blood collection kits directly to patients' homes, and blood can be drawn either by a Natera mobile phlebotomist or at a local blood draw facility
- For a limited time under the program, all out-of-pocket costs associated with testing in any GI malignancy will automatically be managed under Natera's Compassionate Care program, with the vast majority of patients owing zero dollars

Patient Eligibility:

- Recurring / Standing Orders: All GI cancer patients with stage I-III & stage IV oligometastatic disease
  - Adjuvant Setting: <6 months after surgery / curative-intent treatment, up to 4 Signatera tests to inform an adjuvant treatment decision.
  - Surveillance Setting: ≥ 6 months after surgery / curative-intent treatment and in remission / NED
- Single Time Point Orders: All GI cancer patients, any stage

To enroll, please contact your local Natera representative, or email signateracc@natera.com with the subject line "GI Cancer Expanded Access Program."

Finally, Natera provides an essential medical service for thousands of patients every day, and our labs will continue to operate as usual. We have implemented a number of additional safety measures in our lab facilities to ensure the continuity of our testing operations.

We know that these times are difficult and uncertain, and you are likely experiencing new challenges in providing care to your patients. As usual, the Natera team will continue to do everything we can to best serve our patients, health care providers and other partners.

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1. Reinert T, Henriksen TV, Christensen E, et al. Analysis of plasma cell-free DNA by ultradeep sequencing in patients with stages I to III colorectal cancer. JAMA Oncol. 2019;5(8):1124–1131. 2.Coombes RC, Page K, Salari R, et al. Personalized detection of circulating tumor DNA antedates breast cancer metastatic recurrence Clin Cancer Res. 2019;;25(14):4255-426. 3. Abbosh C, Birkbak NJ, Wilson GA, et al. Phylogenetic ctDNA analysis depicts early-stage lung cancer evolution. Nature. 2017;545:446-451. 4. Christensen E, Birkenskamp-Demtroder K, Sethi H, et al. Early detection of metastatic relapse and monitoring of therapeutic efficacy by ultra-deep sequencing of plasma cell-free DNA in patients with urothelial bladder carcinoma. J Clin Oncol. 2019; 37(18):1547-1557.