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Rochester, Minnesota 55905
904-953-0422

Revenue Compliance Office

October 18, 2022

National Government Services, Inc.
NGSnewlcdrequest@anthem.com

RE: Formal Request – New Local Coverage Determination for Cardiology, Ceramides by Liquid Chromatograph-tandem Mass Spectrometry, Plasma, PLA code 0119U

To Whom It May Concern:

Mayo Clinic requests a coverage policy to allow reimbursement for our Ceramides test, under PLA code 0119U: *Cardiology, ceramides by liquid chromatography-tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events*. We believe the test is useful to further risk stratify patients at risk of atherosclerotic events (heart attacks and strokes).

The **relevance** of the Ceramides test is emphasized by the below-mentioned publications and attached to the email request.

Usefulness: Currently there is paucity of tools used to assess patients and understand whether they are at higher or lower cardiovascular risk. Ceramides score identifies this risk and may change management of such patients. The test is reproducible, it can be followed up serially to assess response to treatment or lifestyle interventions since it is modifiable with lifestyle or lipid lowering pharmacologic interventions routinely used by cardiologists. The test also motivates patients to be adherent with provider recommendations.

Clinical health outcomes: Identifying patients at higher risk enables more aggressive management of the risk factors reducing the chance of heart attacks and strokes earlier. These early interventions result in decreased mortality and reduction in hospitalizations for acute coronary syndromes and strokes. This test has clearly showed to be useful for this purpose and decrease negative long-term outcomes as showed in the attached studies.

The statutorily defined Medicare benefit for the requested coverage is under Medicare Benefit Policy Manual, Chapter 15-Covered Medical and Other Health Services, Section 80 - requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests and 80.1–Clinical Laboratory Services.

We have enclosed supplemental materials that address the clinical utility and need for this test. In addition. The test also meets all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Should you have any questions regarding this request, please contact me at (904)-953-0422. Thank you in advance for your consideration of this request.

Respectfully yours,

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cc: Teresa Beard

Resources:

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3. Meeusen JW, Donato LJ, Bryant SC, Baudhuin LM, Berger PB, Jaffe AS. Plasma Ceramides. *Arterioscler Thromb Vasc Biol*. 2018 Aug;38(8):1933-1939. doi: 10.1161/ATVBAHA.118.311199. [PMID: 29903731](#).
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