Update on CMS Molecular Billing Policy “14 Day Rule”

January 15, 2020

As you may be aware, on January 2\textsuperscript{nd}, 2020 the Centers for Medicare & Medicaid Services (CMS) enforcement discretion expired with respect to the laboratory date of service (DOS) exception policy under the Medicare Clinical Laboratory Fee Schedule (CLFS) (See 42 CFR 414.510(b)(5)) (the “14 Day Rule”). The enforcement discretion applied to providers and suppliers with regard to advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests subject to the new laboratory DOS exception policy, as adopted in the CY 2018 Medicare Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule published on December 14, 2017 (See 82 FR 59393).

With the end of the enforcement discretion, hospitals may no longer bill for ADLTs and molecular pathology tests that would otherwise be subject to the new laboratory DOS exception, and it is required that performing laboratories bill Medicare directly for ADLTs and molecular pathology tests subject to the new laboratory DOS exception effective January 1, 2020. The laboratory DOS exception applies only when the following criteria are met:

- The test was performed following a hospital outpatient’s discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter;
- The test was reasonable and medically necessary for the treatment of an illness.

Per the CMS website, “If all of the requirements are met, the DOS of the test must be the date the test was performed, which effectively separates the laboratory test from the hospital outpatient encounter. As a result, the laboratory performing the test must bill Medicare directly for the test, instead of seeking payment from the hospital outpatient department.”

To ensure proper billing, please provide the laboratory with the outpatient admission status, patient demographic and billing information, and applicable ICD-10 or narrative diagnoses. Failure to do so will result in calls to your facility and potentially delayed billing or misdirected charges if we cannot identify patients’ hospital status properly. Tests that are separately billable to Medicare must meet medical necessity requirements established by the payer.
To that end, and to ensure that you have current information on the specific laboratory test codes subject to the laboratory DOS exception, please see the newly-updated summary table Outpatient Billing CPT Code List 01102020 which incorporates updated CPT codes published by Palmetto GBA, our Medicare contractor. You may also visit the CMS website directly at https://care.neogenomics.com/e/434902/-Clinical-Lab-DOS-Policy-html-/j2x1gb/599491025

Additionally, effective January 1, 2020 providers are required to submit Medicare claims with patients Medicare Beneficiary Identifier (MBI), and may no longer submit claims to Medicare with patients Health Insurance Claim Numbers (HICNs). MBIs are 11 characters in length and made up only of numbers and uppercase letters. Please be sure when submitting patient demographics for NeoGenomics to bill Medicare directly that the patients Medicare Beneficiary Identifier is provided. Failure to do so will result in calls to your facility and potentially delayed billing or misdirected charges if we cannot identify patients MBI. For further information on this requirement by Medicare, please visit: https://care.neogenomics.com/e/434902/e-New-Medicare-Card-index-html/rbz344/771061783?h=TSZX7EEdCHjIYVTzeQIK6-pmM9-Dr9_ankvOT1ZGvA

If you have questions regarding this letter and the attachment, please contact your local Territory Business Manager or our Billing department at 866-776-5907 option 2 or avclientbilling@neogenomics.com for more information. Thank you for your continued assistance in complying with these updated Medicare changes.