

Prostate cancer test qualifies for Medicare coverage, 11/14

November 2014—The ConfirmMDx for Prostate Cancer test, from MDxHealth, qualifies for Medicare coverage effective Nov. 3, 2014. The Centers for Medicare and Medicaid Services released the final version of the coverage policy issued by Palmetto GBA: MoIDX title: ConfirmMDx Epigenetic Molecular Assay, LCD No.: L35368.

As part of a commitment to ensure that Medicare covers appropriate use of the ConfirmMDx test, Palmetto GBA expects MDxHealth to continue accruing patients in the prospective, randomized PASCUAL clinical utility trial now in process and to enroll providers into its certification and training registry. The local coverage determination provides for coverage initially limited to patients of physicians enrolled in the ConfirmMDx registry. MDxHealth will conduct an interim analysis of the PASCUAL study to determine the repeat biopsy rate, and expects to complete the interim analysis in 2015. Provided the interim analysis yields positive results showing a substantially lower repeat biopsy rate, Palmetto will expand physician participation in the ConfirmMDx registry, effectively increasing the number of Medicare patients covered. If the interim analysis demonstrates poor accrual, or fails to demonstrate a substantially decreased repeat biopsy rate, the LCD indicates that limited coverage will continue until either 1,200 patients have been tested or three years from the effective date of the LCD, whichever occurs first. MDxHealth expects to have tested 1,200 patients within the PASCUAL trial and the registry by the second quarter of 2016. Unrestricted Medicare coverage, with the registry requirement removed, is expected with favorable PASCUAL trial findings.

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