

Question

Do you know how many NCI or NIH based clinical trials exists and how many medicare beneficiaries may qualify for testing under an LDT NGS assay. The concern is that the coverage under CED would be very limiting in utilization.

Answer(s)

Unclear. NCI match, for ex, does the sequencing in house not via an LDT. CED will be good for access if the issue of labs that can participate is clarified and the registry isn't an issue for providers. Searching Clinical Trials.Gov on the term [national cancer institute] + filtering to exclude trials that were completed, withdrawn, closed enrollment etc. returns 2,052 trials. We don't know how many of the subjects will be Medicare beneficiaries, but the NCD as proposed would grant coverage to all of them. We also note an IOM report from several years ago found Medicare to be the fastest approver of coverage in cancer trials (based on a JHU sample) so we don't anticipate this would be a big problem.

care to comment on definition of ""treating physician""?

The oncologist

Oncologist vs Pathologist?

See above. And, a pathologist is not the treating physician (unless he is literally doing a biopsy on a live patient. The reg is 42CFR 410.32 (a) Basically prevents random docs from churning lab testing via self-referral etc.

FMI is a very expensive test, \$5,800 will this fact be a factor?

CMS does not consider cost in making national coverage determinations, except where Congress has explicitly directed the agency to do so for prevention and screening. It is possible that Medicare will end up paying thousands for an NGS test that might be done far cheaper on a different platform. FDA and coverage policy (the NCD/CED) really have nothing to do with the price tag, we will see what CMS ultimately determines the payment level. It is safe to bet it won't be the list prices.