October 2023

**ASTS Response to CMS Comment on MolDx**

MolDx had always provided broad coverage, which was affirmed by MolDx in public statements from 2017 and 2021, and which was not linked to timing of biopsy or surveillance biopsy protocols.

MolDx has now reversed course in asserting that the use of these tests for surveillance is impermissible. Providers order these tests because of the clinical utility they offer patients as traditional measures for following up transplant function can only detect immune induced changes in the allograft quite late and these tests have a higher sensitivity than routine measurements.

The transplant field is data driven and if future data support decreased test-utilization in specific populations or settings, the transplant community, patients included, will align with those data and recommendations. We are concerned that the administrative process these tests are stuck in will put transplanted organs and transplant patients at risk.

At ASTS, we are cognizant of the need for innovation, cost-control, and patient-centered care and as such would encourage CMS to support the availability of these testing tools to promote patient safety and transplant long term health.

If you have any questions, please do not hesitate to contact Emily Besser, ASTS Associate Director, Advocacy, at Emily.Besser@asts.org.