

## Recommendations for Novel Diagnostics Coverage and Reimbursement

The successful delivery of novel diagnostics is the foundation of personalized medicine, as they are the key tools that allow physicians to differentiate patient-specific characteristics, identify potential preventative measures, and design personalized treatment approaches that maximize clinical benefit while reducing the risk of adverse side effects. Improved health outcomes through personalized medicine should improve patient wellness and bring the costs of healthcare down.

Some of the most pressing challenges for the advent of personalized medicine relate to the reimbursement of novel diagnostics. **Reimbursement policies must reflect the potential benefit that novel diagnostics can bring to patients and the healthcare system.** This value proposition can be realized through reimbursement policy reforms that provide a clear and consistent pathway to obtain affirmative coverage, appropriate and timely coding, and market-based payment for diagnostic tests. BIO recommends that the following reforms be made to diagnostic reimbursement policy:

### Coverage

- **Consistency and Predictability:** In order to achieve consistency and predictability in the coverage determination process, the Centers for Medicare and Medicaid Services (CMS) should clarify the evidentiary standards that must be met by novel diagnostics. CMS manuals should contain criteria that local contractors should consider when contemplating coverage for new diagnostics.
- **Independent diagnostics advisory panel:** Create an independent panel to advise CMS, which would consist of experts who are best suited to comprehensively address policy issues related to diagnostics. This body would advise CMS on issues related to coverage as well as reimbursement assessment regarding the crosswalk and gapfill payment options for diagnostics.

### Coding:

- **Ensure that the coding process is transparent and timely:** Develop a system for assigning temporary codes for novel diagnostics until permanent codes are established so that patients will have greater access to important new diagnostic tests. The coding process should be open and transparent with adequate input from all stakeholders.

### Payment:

**The CMS process for establishing payment rates for new diagnostics should be transparent and predictable. The manufacturer should be able to choose its preferred reimbursement pathway including the existing crosswalk or an enhanced gap-filling methodology, described below. In addition, a new market-based option should be authorized, as described below.**

- **Improved gapfilling option:** Require CMS to base gapfilling pricing procedures on prescriptive factors that include the potential benefit of the test on patient outcomes and to the healthcare system.
- **New payment system option:** Develop a new market-based system that establishes reimbursement methodology for novel diagnostics that reflect both the potential benefit that these tests will have on patient care and the healthcare system, and the value placed upon them in the market.