<table>
<thead>
<tr>
<th><strong>Modernizing regulatory policies</strong></th>
<th><strong>Modernizing coverage and payment policies</strong></th>
<th><strong>Monitor only</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Priority / currently engaged</strong></td>
<td><strong>Monitor / engage if need be</strong></td>
<td><strong>Monitor only</strong></td>
</tr>
</tbody>
</table>
| • Oversight of diagnostic tests (e.g. VALID Act, modifications)*  
  • Engaging user fee amendments reauthorization (e.g. PDUFA, MDUFA) to advance novel clinical trial designs (e.g. decentralized, adaptive trials), patient-focused drug development, patient preferences in medical device evaluation, digital health technologies, real-world evidence, expedited approval pathways, and FDA staffing needs*  
  • Cell- and gene-based therapies  
  • Pharmacogenomic testing (incl. STRIPE Collaborative Community in pharmacogenomics)  
  • Tracking FDA approvals and market authorizations | • Co-development of diagnostics and drugs*  
  • Biomarker qualification  
  • Genetic non-discrimination (e.g. GINA)  
  • Artificial intelligence/machine learning-based diagnostics  
  • Digital biomarkers  
  • Direct-to-consumer genetic tests  
  • Patent protection and intellectual property law  
  • Global regulatory policies (harmonize with FDA)  
  • Orphan Drug Designation | |
| • Genetic and genomic testing services (e.g. Sec. 407 of Cures 2.0)*  
  • Payment models incentivizing innovation (e.g. value-based and outcomes-based payment, alternative payment models, CMMI demos impacting Part D and Part B; guardrails for CMMI; financing high-price, high-impact therapies; Oncology Care First payment model)*  
  • Novel approaches to facilitating coverage and reimbursement (e.g. successor to MCIT pathway, parallel review)  
  • Ensuring drug pricing proposals do not endanger access to PM (e.g. reference pricing/ “Most Favored Nation,” Part B to Part D Switch) | • Diagnostic testing (e.g. clinical lab fee schedule, laboratory date of service policy, PAMA implementation)*  
  • Next generation sequencing diagnostic tests (e.g. NCD for NGS in Advanced Cancer)*  
  • Preventive screening and early disease detection  
  • Benefit design reforms (e.g. prior authorization for diagnostics, step therapy)  
  • Cell- and gene-based therapies (e.g. CAR-T)  
  • Telehealth and remote/home-based care | |
| | | |
## PMC 2022 Policy Agenda

<table>
<thead>
<tr>
<th>Priority / currently engaged</th>
<th>Monitor / engage if need be</th>
<th>Monitor only</th>
</tr>
</thead>
</table>
| **Advancing innovation in care delivery and value of personalized medicine** | • Use of real-world evidence*  
• Clinical guidelines  
• Value assessment frameworks and methodologies  
• Advancing a patient-centered outcomes research agenda for PM  
• NAS study on use of genetic/genomic testing to improve outcomes  
| • Clinical trial enrollment rates; diagnostic testing treatment arms in trials  
• Utilization management (e.g. clinical-decision-making tools)  
• Quality measures  
• Tissue-agnostic diagnosis and treatment  
• De-identified data  
• Interoperability and data management  
• Access to genetic counselors (e.g. Access to Genetic Counselor Services bill)  | • Expanded role for pharmacists |
| **Cultivating support for personalized medicine** | • Congressional Personalized Medicine Caucus*  
• Cures 2.0*  
• Diversity and inclusion in research, clinical trials  
• FDA appropriations  
• NIH appropriations  
| • New initiatives in Biden administration (e.g. ARPA-H)  |  |

* an asterisk indicates PMC members rated this issue as a high priority

### Additional Resources

- For more information on PMC’s previous work on these topics, please visit the “Policy” section of our website [here](#). The issue categories in the left sidebar will direct you to respective archives of comments.
- This policy agenda relates mainly to PMC’s advocacy activities. More information about PMC’s initiatives in education and evidence development, are outlined in our [2022 Strategic Plan](#).
- PMC has multiple forums convening its members to discuss policy issues and advocate for personalized medicine. This includes the Public and Science Policy Committees; working groups convening patients, industry, and health care professionals; as well as working groups for special projects. For more information about these forums, please visit our website [here](#) and contact David Davenport at [ddavenport@personalizedmedicincoalition.org](mailto:ddavenport@personalizedmedicincoalition.org) to join. We also encourage you to let us know if you have subject matter expertise on a specific policy issue above.