

# UCSF

## UC San Francisco Previously Published Works

### Title

Insurance coverage for genomic tests

### Permalink

<https://escholarship.org/uc/item/44x34931>

### Journal

Science, 360(6386)

### ISSN

0036-8075

### Authors

Phillips, Kathryn A  
Trosman, Julia R  
Deverka, Patricia A  
[et al.](#)

### Publication Date

2018-04-20

### DOI

10.1126/science.aas9268

Peer reviewed

adopting the structured process we propose.

**Duan Biggs,<sup>1\*</sup> Robert J. Smith,<sup>2</sup> Vanessa M. Adams,<sup>3</sup> Henry Brink,<sup>2</sup> Carly N. Cook,<sup>4</sup> Rosie Cooney,<sup>5</sup> Matthew H. Holden,<sup>6</sup> Martine Maron,<sup>6</sup> Jacob Phelps,<sup>7</sup> Hugh P. Possingham,<sup>8</sup> Kent H. Redford,<sup>9</sup> Robert J. Scholes,<sup>10</sup> William J. Sutherland,<sup>11</sup> Fiona M. Underwood,<sup>12</sup> E. J. Milner-Gulland<sup>13</sup>**

<sup>1</sup>Griffith University, Nathan, QLD 4111, Australia.

<sup>2</sup>University of Kent, Canterbury, CT2 7NR, UK.

<sup>3</sup>Macquarie University, Sydney, NSW 2109, Australia.

<sup>4</sup>Monash University, Clayton, VIC 3800, Australia.

<sup>5</sup>IUCN SULI, 1196, Gland, Switzerland. <sup>6</sup>University of Queensland, St. Lucia, QLD, 4072, Australia.

<sup>7</sup>Lancaster University, Lancaster, UK. <sup>8</sup>The Nature Conservancy, Arlington, VA 22203, USA. <sup>9</sup>Archipelago Consulting, Portland, ME 04112, USA. <sup>10</sup>University of Witwatersrand, Johannesburg, South Africa.

<sup>11</sup>University of Cambridge, Cambridge, CB2 3EJ, UK.

<sup>12</sup>Taunton, UK. <sup>13</sup>Oxford University, Oxford, OX2 6GG, UK.

\*Corresponding author. Email: [ancientantwren@gmail.com](mailto:ancientantwren@gmail.com)

#### REFERENCES

1. M. 't Sas-Rolfes, B. Moyle, D. Stiles, *Pachyderm* **55**, 62 (2014).
2. R. B. Martin *et al.*, "Decision-making mechanisms and necessary conditions for a future trade in African elephant ivory" (CITES, 2012).
3. CITES, "A statement from the MIKE and ETIS Technical Advisory Group on recent claims that the CITES-approved ivory sales in 2008 caused a spike in poaching levels" (2017); <https://cites.org/sites/default/files/eng/cop/17/InfDocs/E-CoP17-Inf-42.pdf>.
4. R. Duffy, *Environ. Planning C Gov. Pol.* **31**, 222 (2013).
5. D. Kahan, *Nature* **463**, 296 (2010).

6. D. M. Kahan *et al.*, *Nat. Clim. Change* **2**, 732 (2012).
7. B. Moyle, *Ecol. Econ.* **107**, 259 (2014).
8. S. M. Hsiang, N. Sekar, "Does legalization reduce black-market activity? Evidence from a global ivory experiment and elephant poaching data," National Bureau of Economic Research (Working Paper no. 22314, 2016).
9. S. N. Stuart *et al.*, *Oryx*, 10.1017/S0030605317001557 (2017).
10. CITES, "Closure of domestic markets for elephant ivory" (COP17 Doc 57.2, 2016); <https://cites.org/sites/default/files/eng/cop/17/WorkingDocs/E-CoP17-57-02.pdf>.
11. CITES, "Consideration of proposals for amendment of Appendices 1 and 2" (2016); <https://cites.org/sites/default/files/eng/cop/17/E-CoP17-Prop-14.pdf>.
12. A. Kahane, K. Van Der Heijden, *Transformative Scenario Planning: Working Together to Change the Future* (Berrett-Koehler Publishers, 2012).
13. D. H. Cole, *Nat. Clim. Change* **5**, 114 (2015).
14. CITES, "African range States agree a restricted ivory trade from four southern African countries" (2002); [https://cites.org/eng/news/pr/2002/021102\\_eledialogue.shtml](https://cites.org/eng/news/pr/2002/021102_eledialogue.shtml).
15. CITES 17.89-17.91, "Specimens produced from synthetic or cultured DNA" (2017); [www.cites.org/eng/dec/valid17/81839](http://www.cites.org/eng/dec/valid17/81839).

10.1126/science.aat1596

## Insurance coverage for genomic tests

On 16 March, the Centers for Medicare and Medicaid Services (CMS) announced that Medicare will cover Food and Drug Administration (FDA)-approved or cleared genomic tests that encompass broad gene

panels for advanced cancer patients (1). The final policy does not include the initial draft's proposed "coverage with evidence development" (CED)—i.e., coverage of tests run as part of clinical trials and registries—which some had argued should be applied to develop a stronger evidence base for these tests (2). Instead, tests not already approved in the national coverage determination can be reviewed for coverage by local Medicare Administrative Contractors (MACs). The new policy reflects a substantial shift in determining how genomic tests are evaluated for coverage, which provides a needed "roadmap" for coverage. However, to develop effective and efficient policies, stakeholders should support further research to address how the new policy will affect ongoing cancer research as well as the access to and affordability of next-generation sequencing testing for cancer patients.

The new policy has the potential to increase access to testing, but it may remain out of reach for many patients. Private payers may not follow the CMS policy for covered tests, as there are myriad reasons that payers have limited their coverage for broad genomic tests

(3), and private payers often do not use Medicare policies as precedents (4). The tests that remain uncovered by CMS may not be covered by local MACs either (5). The numerous laboratories that offer their own tests that do not currently meet the coverage requirements in the new policy may have trouble finding the trial participants and funding they need to obtain the evidence required. Although CMS's policy may spur these laboratories to develop evidence even without a CED requirement, this process may take several years, and its outcome is uncertain (4). The CMS policy is binding only on Medicare; it is uncertain whether states will cover these tests for Medicaid patients (6).

Likewise, the policy may increase affordability and equity for these tests, but with caveats. Benefit-cost tradeoffs were not examined as they are outside the scope of CMS. CMS is caught in an ongoing dilemma: Coverage policies are determined irrespective of cost, yet there is a constant drumbeat of calls to reduce Medicare expenditures (7). Lastly, it will be important to understand the implications of the new policy for genomic tests for patients with other types of cancer and with other

conditions, which face similar challenges to coverage (8).

Given today's challenging health policy environment, CMS should work with stakeholders, including other federal agencies, to carefully evaluate the benefits and risks of this novel coverage approach and to consider what additional policy mechanisms will be needed to ensure that the necessary evidence is generated. We must address the substantial uncertainty about the impact of coverage policies on the health outcomes of Medicare beneficiaries.

**Kathryn A. Phillips,<sup>1,2,3</sup> Julia R. Trosman,<sup>4</sup> Patricia A. Deverka,<sup>1,5</sup> Bruce Quinn,<sup>6</sup> Sean Tunis,<sup>7</sup> Peter J. Neumann,<sup>8</sup> James D. Chambers,<sup>8</sup> Louis P. Garrison Jr.,<sup>9</sup> Michael P. Douglas,<sup>1</sup> Christine B. Weldon<sup>4</sup>**

<sup>1</sup>Department of Clinical Pharmacy, Center for Translational and Policy Research on Personalized Medicine (TRANSPERS), University of California San Francisco, San Francisco CA 94143, USA. <sup>2</sup>Philip R. Lee Institute for Health Policy, San Francisco, CA 94118, USA. <sup>3</sup>Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, San Francisco, CA 94143, USA. <sup>4</sup>Center for Business Models in Healthcare, Northwestern University Feinberg School of Medicine, Chicago, IL 60611 USA. <sup>5</sup>American Institutes for Research, Chapel Hill, NC 27517, USA. <sup>6</sup>Bruce Quinn Associates, Los Angeles, CA 90036, USA. <sup>7</sup>Center for Medical Technology Policy (CMTP), Baltimore, MD 21202, USA. <sup>8</sup>The Center for

the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA 02111, USA. <sup>9</sup>The Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute, Department of Pharmacy, University of Washington, Seattle, WA 98195, USA.

\*Corresponding author. Email address: kathryn.phillips@ucsf.edu

#### REFERENCES

1. CMS, Decision Memo for Next-Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) (2018); [www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290&DocID=CAG-00450N&bc=AAAAAAAQAAA&](http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290&DocID=CAG-00450N&bc=AAAAAAAQAAA&).
2. R. Eisenberg, H. Varmus, *Science* **358**, 1133 (2017).
3. K. A. Phillips *et al.*, *Nat. Biotechnol* **35**, 614 (2017).
4. J. D. Chambers *et al.*, *Health Aff. (Millwood)* **34**, 1376 (2015).
5. D. R. Levinson, "Local coverage determinations create inconsistency in Medicare coverage" (2014); <https://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf>.
6. E. Schattner, "Medicare will cover genetic cancer testing, with caveats," *Forbes* (2018); [www.forbes.com/sites/elaineschattner/2018/03/16/medicare-will-cover-genetic-cancer-testing-with-caveats/#d78931d9e556](http://www.forbes.com/sites/elaineschattner/2018/03/16/medicare-will-cover-genetic-cancer-testing-with-caveats/#d78931d9e556).
7. P. J. Neumann, J. D. Chambers, *N. Engl. J. Med.* **367**, 1775 (2012).
8. J. R. Trosman *et al.*, *J. Natl. Compr. Canc. Netw.* **15**, 219 (2017).

#### ACKNOWLEDGMENTS

This letter was funded by grants from the National Human Genome Research Institute (R01HG007063 and U01HG009599) and by the Helen Diller Family Comprehensive Cancer Center Support Grant of the National Institutes of Health under Award Number P30CA082103-18.

10.1126/science.aas9268

## Insurance coverage for genomic tests

Kathryn A. Phillips, Julia R. Trosman, Patricia A. Deverka, Bruce Quinn, Sean Tunis, Peter J. Neumann, James D. Chambers, Louis P. Garrison Jr., Michael P. Douglas and Christine B. Weldon

*Science* **360** (6386), 278-279.  
DOI: 10.1126/science.aas9268

### ARTICLE TOOLS

<http://science.sciencemag.org/content/360/6386/278>

### REFERENCES

This article cites 5 articles, 3 of which you can access for free  
<http://science.sciencemag.org/content/360/6386/278#BIBL>

### PERMISSIONS

<http://www.sciencemag.org/help/reprints-and-permissions>

Use of this article is subject to the [Terms of Service](#)

---

*Science* (print ISSN 0036-8075; online ISSN 1095-9203) is published by the American Association for the Advancement of Science, 1200 New York Avenue NW, Washington, DC 20005. 2017 © The Authors, some rights reserved; exclusive licensee American Association for the Advancement of Science. No claim to original U.S. Government Works. The title *Science* is a registered trademark of AAAS.