

Evidence Roadmap: Medicare Trends in Specialty Drug Costs and Use



AcademyHealth

In 2013, AcademyHealth's Translation and Dissemination Institute launched its Listening Project, which aims to identify the most pressing health services research needs of leaders in health policy and health care delivery for the coming three to five years. **The 2014 Listening Project Report** identified several research and data gaps related to Medicare. In response to what we heard from the Medicare policy community, AcademyHealth has created this series of evidence roadmaps to identify existing resources related to the gaps. These roadmaps represent a selected minimal set of key resources rather than a comprehensive list of relevant research. The roadmaps are intended to help policy analysts and other research users better understand whether a perceived research gap represents an actual lack of evidence or failure of existing evidence to reach the policy arena, that is, a failure of adequate translation and dissemination. AcademyHealth undertook this roadmap with the support of the Robert Wood Johnson Foundation.

In their Listening Project interviews, members of the Medicare policy community suggested a particular need for policy-relevant research focused on the growing number of costly “specialty drugs” – often biologics* – to treat conditions that affect a relatively small number of people. Specialty drugs, including biologics, tend to be expensive and might pose a significant cost burden to Medicare. Policymakers are interested in ways to maintain access to safe and effective drugs for patients while containing cost growth. Research on the potential use of biosimilars, generic forms of biologics, and the cost impact of specialty drugs on consumers exists, but biosimilars are a new concept in U.S. policy, therefore, more research will be forthcoming with time.

Individual Studies

The Market for Follow-On Biologics: How will it Evolve?

Grabowski H, Cockburn I, Long G. *Health Aff (Millwood)*. 2006 Sep; 25(5): 1291-1301.

Authors examined the growth of biologics and the potential for follow-on biologics. Authors also discussed price competition and innovation incentives.

Biosimilars and the European Experience: Implications for the United States

Merglin F, Lopert R, Taymore K, Trouvin J. *Health Aff (Millwood)*. 2013 Oct; 32(10): 1803-1810.

This study analyzed the European Union's regulation of biologics and their experience with biosimilars. The authors discussed implications of the European experience for the United States biologic market, including possible impacts of biosimilars on competition and cost. This study was not Medicare specific.

Grey Literature

Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier

Dicken JE, Simerl W, Howard K, MacDonald A, Samuel C, Zose M, et al. (Government Accountability Office, Washington D.C.). 2010 Jan. Report No.: GAO-10-242.

This report provided information about high-cost drugs eligible for a specialty-tier. It discussed how different cost sharing structures and negotiated drug prices might impact beneficiary out-of-pocket costs.

Specialty Tiers: Benefit Design Considerations for Medicare Part D

Dieguez G, Pyenson B, Johnson R. Milliman Client Report; 2013.

This actuarial report provided background on Medicare Part D plans use of specialty tiers and the costs to Medicare associated with specialty drugs.

Report to the Congress: Medicare Payment Policy

Medicare Payment Advisory Commission (MEDPAC). March 2014 Washington, D.C.; 2014 p. 355-390.

This standard chapter in the annual March Medicare Payment Advisory Commission (MEDPAC) report provides an overview of current issues and recent trends associated with Medicare Part D.

2014 Specialty Drug Benefit Report

Pharmacy Benefit Management Institute. 2014 Specialty Drug Medicare Benefit Report. Plano, TX: Pharmacy Benefit Management Institute; 2014.

This report, which is not specific to Medicare, presented findings from a 2014 Pharmaceutical Benefit Management Institute (PBMI) survey of strategies related to specialty drug insurance benefit design and management. PBMI is a membership organization serving health care purchasers, pharmacy benefit managers, and other industry professionals involved in the delivery of drug benefits.

Health Policy Brief: Biosimilars. Robert Wood Johnson Foundation and Health Affairs

Richardson E. (US); 2013 Oct 10.

This policy brief outlined the debate surrounding the Biologics Price Competition and Innovation Act, part of the ACA. It discusses the potential impact of biologics and competition in the biologic market on drug spending.

Health Policy Brief: Specialty Pharmaceuticals. Robert Wood Johnson Foundation and Health Affairs

Spatz I, McGee N. (US); 2013 Nov.

This policy brief discussed specialty pharmaceuticals and their relationship to spending growth. This brief includes a background on the various topics associated with specialty pharmaceuticals, like biosimilars and cost sharing, and a discussion of the future of specialty pharmaceuticals.

Limited Options to Manage Specialty Drug Spending

Tu HT, Samuel DR (Center for Studying Health System Change, Washington D.C.). 2012 Apr. Report no. 22.

This research brief discussed the rise of specialty drug use, including the use of biologics. It highlights cost implications for overall health care spending and various innovations to control spending related to specialty drug use. This study is not Medicare specific.

Strategic Analysis and Intelligence Report: The Tier 4 Phenomenon: Shifting the High Costs of Drugs to Consumers

Walsh B (AARP, Washington D.C.). 2009 Mar.

This report discussed the cost impact of “fourth tier” specialty drugs on consumers, particularly Medicare beneficiaries.

Search Strategy

AcademyHealth staff first identified key words and associated MeSH (medical subject headings) terms using the National Library of Medicine MeSH browser. Staff used the key words to search various databases and journals for relevant articles, and then examined the bibliographies of these articles to identify additional studies. Staff searched health care, health policy, trade group, government, and academic websites for grey literature and chose studies most relevant to new trends in pharmaceuticals, in the context of Medicare. Because the purpose of these roadmaps was to inform current policy, searches focused on years 2010 through 2014, with older resources included when appropriate. Two AcademyHealth members, chosen for their relevant expertise, reviewed the draft Roadmap, and AcademyHealth staff then updated the document to incorporate the reviewers' comments and suggestions.

Databases/Journals: EBSCO Host—Academic Search Elite, Business Source Elite; SAGE Publications; PubMed/MEDLINE; Medical Care Research and Review; Health Affairs; HSRProj; Google Scholar

Websites: Kaiser Family Foundation; AARP Public Policy Institute; Altarum Institute; Alliance for Health Reform; Robert Wood Johnson Foundation; Commonwealth Fund

Key words: biologics; biologics AND elderly; biologics AND Medicare; specialty drugs; specialty drugs AND elderly; specialty drugs AND Medicare

Inclusion criteria: Studies/resources related to use of biologics (or “specialty drugs”) and implications for Medicare

Key to Cited Resources

 **Individual studies** provide findings from key pieces of research.

 **Grey literature** provides relevant evidence published by organizations whose primary activity is not publishing.

* For a discussion of biologics (also known as biopharmaceuticals) and how they differ from conventional drugs, see: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm>.