

Specialty Pharmaceuticals: An Agenda for Health and Productivity Research

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The issue

Specialty pharmaceuticals are medications that treat complex and serious or life-threatening conditions. Examples of such conditions include multiple sclerosis, hepatitis C, cancer, rheumatoid arthritis, inflammatory bowel disease, human immunodeficiency virus (HIV)/AIDS, and pulmonary hypertension. Specialty pharmaceuticals have relatively high costs per unit, often require special handling, and involve intensive ongoing clinical assessment.¹⁻⁵

Specialty pharmaceuticals currently comprise the fastest-growing sector of the pharmacy market.^{6,7} In many cases, they represent the most effective—and sometimes the only—option for treating or curing serious or life-threatening diseases. Their therapeutic values notwithstanding, specialty pharmaceuticals recently have garnered attention for their costs, which can exceed \$100,000 a year for some treatments.³ According to a 2014 Kaiser Family Foundation report, the percentage of employer-sponsored benefit plans with specialty pharmacy tiers—in which patients' copayment and coinsurance costs are higher than for other medications—grew from 14% in 2012 to 20% in 2014.² The average copayment for specialty medications was \$83, compared with \$31 for preferred brand name drugs with no generic substitute. Average coinsurance rates were 29% and 24%, respectively.²

The cost of specialty pharmaceuticals raises concerns that patients will find effective treatments unaffordable, especially if they are enrolled in high-deductible health-care plans or plans that do not have out-of-pocket maximums.⁸ Some argue that the “savings” from foregone treatments may be illusory if untreated conditions contribute to the use of other high-cost treatments—for example, liver transplants in the case of untreated hepatitis C.

The lost productivity implications of serious or life-threatening conditions are absent from most discussions of specialty pharmaceuticals' value. For example, statistics are vague on how many people do not participate in the labor force because of a serious illness, but could

perhaps participate with the help of specialty treatments. Household earnings, payroll tax receipts, and the use of public safety-net programs, such as Medicaid and Social Security Disability Insurance, are all affected by such lost productivity. Additionally, the incidence, wage replacement, and lost-productivity costs of sick-day and disability leaves due to untreated serious illness have not been considered fully. Therefore, decisions made about the cost-effectiveness of specific specialty pharmaceuticals likely have occurred without a full accounting of their benefits to patients, their employers, and society at large.

What is the evidence for workforce productivity?

There is reason to expect that effective treatments could have a positive productivity impact. Studies show that several conditions targeted by specialty medications are costly in terms of work outcomes, such as labor force participation, illness absence, disability leave,⁹ and job performance. These conditions include hepatitis C,¹⁰ rheumatoid arthritis,¹¹ multiple sclerosis,¹² a variety of cancers,¹³ and HIV/AIDS.¹⁴ Medications that help restore functioning for patients with such conditions would therefore have a value that is not captured by treatment costs.

What are the evidence gaps?

While medication adherence has been linked to better work outcomes for several chronic health conditions,¹⁵ few studies have examined the productivity impact of specialty pharmaceuticals. With the exception of rheumatoid arthritis^{11,16} and hemophilia,^{17,18} evidence describing patients' work experiences before and after treatment with specialty pharmaceuticals is lacking. Few basic studies exist that describe symptomatic work limitations (such as fatigue among multiple sclerosis patients) that are not easily addressed by return-to-work or stay-at-work accommodations.

For specific conditions targeted by specialty pharmaceuticals, basic health and productivity research questions that remain unanswered include:

PRACTICAL IMPLICATIONS

- Specialty pharmaceuticals that help patients participate fully in the labor force may have economic and social benefits that offset some of their prescription costs.
- Few studies of specialty pharmaceuticals incorporate work outcomes such as employment, disability and sick-day absences, or job performance.
- A broad, intensive research agenda including both quantitative and qualitative methods is recommended to provide stakeholders such as employers, policymakers, and patients' groups with empirical evidence on which to formulate specialty pharmaceutical policies.

- How many people have limited labor force participation because of their condition?
- How do earnings, payroll taxes, receipt of public safety-net benefits, unemployment rates, and under-employment rates for people treated with a specialty pharmaceutical (ie, a treatment cohort) compare with those for people with the same condition receiving usual care or no care (ie, control cohorts)?
- How do work absences, disability leaves, and job performance (measured by survey responses, objective task standards, supervisor ratings, etc) for employed persons in a specialty pharmaceuticals cohort compare with those of employees in control cohorts?
- How do wages, labor force participation, work absences, disability leaves, and job performance change before and after treatment with a specialty pharmaceutical, and how do these differences compare to those for control cohorts over the same time period?
- What is the projected total economic value of a specialty pharmaceutical in terms of improvements in labor force, wage, payroll taxes, public social benefits, and productivity outcomes relative to the costs of the treatments, and how does this compare with usual care or no care?

Advanced research questions could include:

- What physical, social, and financial barriers do people with a given condition face in obtaining employment, remaining on the job, and performing work tasks according to expected standards? Which of these barriers could be overcome, effectively, through treatment with specialty pharmaceuticals?
- What challenges do employers face in accommodating the needs of employees with conditions targeted by specialty pharmaceuticals? How might the availability of specialty pharmaceuticals alleviate some of the challenges?
- What kinds of information do employers and policymakers currently consider when assessing the

short- and long-term economic and social value of specialty pharmaceuticals?

What kind of research could close the evidence gaps?

Several research approaches could close knowledge gaps about the productivity impact of specialty pharmaceuticals. These include:

- Analyses of nationally representative data with workforce participation and household earnings for households in which a head or spouse suffers from conditions targeted by specialty pharmaceuticals.
- Analyses of integrated, longitudinal medical, pharmacy, and disability claims data.
- Inclusion of work outcomes such as employment status, absences, disability leaves, and validated job performance instruments in randomized controlled trials of specialty pharmaceuticals.
- Work diaries collected from employees before, during, and after specialty treatment regimens.
- Interviews with patients and providers about work challenges related to specific conditions targeted by specialty pharmaceuticals.
- Focus groups of benefits managers to discuss information used when making decisions about specialty pharmacy tiers.
- Case studies or expert interviews with employers that have expanded or contracted healthcare beneficiaries' access to specialty pharmaceuticals.
- Employer surveys of barriers to specialty pharmaceutical coverage.

Conclusions

Existing studies show that several chronic health conditions targeted by specialty pharmaceuticals impact patients' abilities to participate fully in the labor force. Treatments that help patients manage debilitating illness symptoms therefore may have economic and social benefits that offset some of their prescription costs.

However, empirical evidence to establish the economic and social value that specialty pharmaceuticals might provide among different groups of patients is limited by a lack of focused research. It is unclear how effective treatments might facilitate return-to-work or stay-at-work accommodations, or promote labor force participation more generally.

Given these knowledge gaps, a broad, intensive research agenda including both, quantitative and qualitative methods, is recommended. The questions and research



approaches described in this commentary are not comprehensive. Nonetheless, they provide a foundation for a feasible research agenda on the overall costs and benefits of specialty pharmaceuticals. Cumulatively, the findings could provide stakeholders such as employers, policy-makers, and patients' groups with empirical evidence on which to formulate specialty pharmaceutical policies.

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