

Purpose

The purpose of this statement is to express ACCP's position on optimal specialty drug use. It reflects ACCP's belief that comprehensive medication management is necessary to achieve optimal medication use and evidence-based pharmacotherapy outcomes for patients and the health care system in the use of medications commonly called specialty drugs.

The American College of Clinical Pharmacy

1. Supports specialty drug pricing models that ensure that patients and health systems receive commensurate value from the appropriate use of specialty drugs, employ rational and transparent pricing practices, and enable pharmaceutical manufacturers to sufficiently recoup research and development (R&D) investments.
2. Believes that comprehensive medication management¹ applied through standardized clinical practice processes² is a cornerstone of interprofessional, patient-centered care that can better ensure optimized specialty drug use.
3. Supports the technological advances (e.g., genome sequencing, enhanced diagnostic testing capabilities) that have fundamentally altered pharmaceutical sciences research and new product development and fostered unprecedented therapeutic innovation in specialty drugs, including those targeting specific biomarkers or genotypes, novel agents for rare diseases (e.g., cystic fibrosis or Gaucher disease), biosimilars, and interchangeable biologic products.
4. Believes that specialty drug pricing models, regulatory mechanisms, and systems for product access and distribution should align with desired clinical outcomes to best promote health care affordability, quality, safety, and access for patients.
5. Advocates for further research on value-based pricing models and other explicit analyses of specialty drug cost, value, comparative effectiveness, and safety.

Definitions

Specialty drugs	Medications that have a total average cost greater than \$1000 per prescription or an average daily cost greater than \$33 per day. ³
Comprehensive medication management (CMM)	The standard of care that ensures that a patient's medications are individually assessed to determine that each is appropriate; effective for the patient's medical condition(s); safe, given any comorbidities and other medications present; and able to be taken by the patient as intended. ¹
Value-based pricing	A process used to apply evidence for medication-derived improvement in patient outcomes to determine the price for that medication (compared with other treatment options). ⁴

Background

The often-astounding price of many existing and newly approved specialty drugs is a major and growing concern to patients, the American public, commercial and federal payers, and health policy analysts and regulators. Among the various solutions proposed to address this concern are governmental price controls on manufacturers, efforts to develop and validate “value-based pricing models,” and the trend toward shifting these and other health care costs directly to patients in the form of higher insurance premiums, deductibles, co-insurance, and co-payments.

Because no definition of specialty drugs has uniformly been embraced in health care, use of the term throughout this statement is derived from a recent AARP research report that defines specialty prescription drugs as a prescription drug that “has a total average prescription cost greater than \$1,000 per prescription; or has a total average cost per day of therapy greater than \$33 per day.”³ The Centers for Medicare & Medicaid Services definition of specialty drugs is also based on price—pharmaceuticals costing \$600 or more per month are considered specialty drugs.⁵

Pharmaceutical manufacturers have traditionally set prices according to proprietary business practices. However, competitive market forces commonly affect medication prices to some extent. These include privately negotiated discounts and rebates for insurers, payers, and pharmacy benefit managers, which, according to IMS Health, explains the difference between “list” and “net” price growth, which measured 12% and 2.8%, respectively, in 2015.⁶ Substantially less competition exists in the specialty drug market than in this traditional market, driving initial pricing higher and significantly affecting both patients and payers.

Citing figures from industry-funded research, pharmaceutical manufacturers regularly suggest that the cost to bring a new drug to market exceeds \$2.5 billion. However, the rigor of the methodology underlying this figure has been disputed.^{7,8} The policy platform for the Campaign for Sustainable Rx Pricing asserts that there is “no way of determining how much pharmaceutical companies actually invest in [R&D] activities.”⁹ The platform document further asserts: “Manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of federal spending on the product.”⁹

In addition to advocating for enhanced transparency and value-based specialty drug pricing, placing sustained emphasis on expanding the underlying evidence base for the overall health system value of specialty drugs remains imperative. Independent cost-effectiveness evaluations and cost-utility analyses can provide clinicians and payers with deeper insight into the potential economic impact of specific treatments as well as their clinical impact. Recent examples include published evaluations of oncologic,^{10,11} cardiovascular,¹² and neurologic treatments,¹³ among others. Ongoing investigation must continue in this regard, given the sweeping federal and state health policy changes that are expected over the next 3–4 years.

As of this position statement, no formal policy or position statements specifically addressing specialty drug pricing methodologies have been published by national pharmacy or primary care medical organizations.¹⁴⁻¹⁷

The fundamental and historical commitment of pharmacists to ensure the “right prescription for the right patient” requires a significant conceptual reformulation in the particular case of specialty drug decision-making and use. Specifically, primary attention to identifying and selecting “the right patient for a specialty drug,” using the patient-centered, team-based, and evidence-driven approach of comprehensive medication management, must consistently be paired with emerging value-based pricing approaches to better ensure that the rational and economical use of specialty drugs is optimized both for patients and for the health care system.

**Approved by the ACCP Board of Regents
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