Management of Specialty Drugs, Specialty Pharmacies, and Biosimilars in the United States

Richard A. Brook, MS, MBA[1,2]; Jim E. Smeeding, RPh, MBA[1,3]; Jeff A. Carlisle, BA[1,3]; Michael J. Sax, PharmD[3]

[1]TPG-National Payor Roundtable, Glastonbury, CT; [2]Better Health Worldwide, Newfoundland, NJ; [3]The Pharmacy Group, Glastonbury, CT

TPG National Payor Roundtable (TPG-NPRT) focuses on market access programs within the United States, is a subsidiary of The Pharmacy Group, and maintains a database of Chief Medical Officers and Chief Pharmacy Officers in the United States.

Better Health Worldwide provides evidence-based research and support to the healthcare industry. We partner with pharmaceutical and device manufacturers to develop and conduct domestic and international clinical-based advisory board programs, conduct retrospective research and communicate findings with an emphasis on outcomes, absenteeism and the impact of conditions on caregivers.

The Pharmacy Group provides consulting services to the healthcare and pharmaceutical industry.

BACKGROUND

- Specialty Pharmacy (SP) products:
  - Treat specific, complex, and chronic diseases
  - Are costly, require reimbursement, have handling assistance & training, have unique and limited distribution processes, and frequently have patient-adherence programs
- Based on the 12 months ending June 2018, Specialty Pharmaceutical[1]:
  - Expenditures continue to grow and reached 44.5% of the non-discounted spending during this period (up from 31.5% in 2013)
    - The top specialty products (rank, sales in billions) include: Humira (#1, $17.5), Remicade (#2, $8), Enbrel (#3, $5.4)
  - Are often managed by biologic agents and seven of the top 20 specialty products have biosimilar products in the market or in development
- Currently, in the US Market: 16 biosimilars have been approved since 2015, only 7 products are marketed, representing biosimilars of[2]:
  - Neupogen® (Filgrastim): marketed as Zarxio® by Sandoz and as Nivestym™ by Pfizer
  - Remicade® (Infliximab): marketed as Inflectra® by Celltrion/Pfizer and as Renflexis® by Samsung Bioepis/Merck
  - Epogen® (Epoetin): marketed as Retacrit® by Pfizer
  - Neulasta® (Pegfilgrastim): marketed as Fulphila™ by Biocon/Mylan and as Udenyca™ by Coherus
- Based on recent programs with US payors, Medical Directors and sponsors (pharmaceutical, medical device, and health technology companies), the authors and their organizations decided to conduct a survey of Medical and Pharmacy Directors involved with Pharmacy & Therapeutics (P&T) Committees on their policies regarding:
  - Specialty Pharmacy products
  - Use of Specialty Pharmacies
  - Expectations for biosimilar use and savings
  - Prescribers and member biosimilar education

OBJECTIVES

- To gain a better understanding of health plan management of SPs, SP products, and biosimilars today and compare with prior surveys
- The survey focused on:
  - Top SP products and co-pays
  - Biosimilar coverage, co-pays and expected savings over time
  - Expectations for prescribers and member biosimilar education

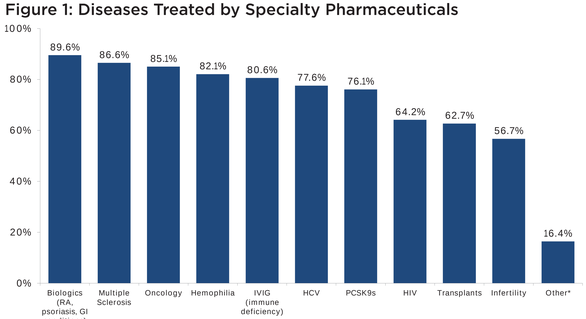
METHODS

- An online, interactive survey was developed with 79 questions
- Invitations to participate were sent to Medical and Pharmacy Directors working with US health plans, Pharmacy Benefit Managers (PBMs), and insurers from the TPG-NPRT database in November 2018
  - Material or financial incentives were not offered for completion of the survey
- Survey responses were compared with prior surveys and changes ≥2% are reported

RESULTS

- A total of 85 respondents (12.8% response rate) completed the survey, some questions were not answered by all respondents
- 36.9% worked for health plans, 13.1% PBMs, 9.5% Integrated Delivery Networks (IDNs), 2.4% for Preferred Prescriber Organizations (PPOs) / Independent Provider Associations (IPAs), 1.2% for the Government, the remainder consultants
- 29.9% of plans were national, 24.7% were regional and 22.1% were local
- The most commonly reported respondent titles were: Chief / Senior Officer (42.9%), Regional (13.1%), Payor specific (8.3%), or therapeutic area specific (1.2%)
- Plans cover multiple types of members: Employer/Self-funded=79%, Medicaid (Traditional=27.8%, HMO/PPO=72.3%), Commercial (58.6%=FFS, 77.8%=HMO/PPO), Medicare (71%,PDP-only=51%), IDN (43.6%, 340B Qualified=43.8%)
- The use of Specialty Pharmacies is restricted by 58% of plans (81% last year) currently, advisors report:
  - Specialty Pharmacy use is restricted by: 58% of plans to those under contract, 11.8% for products available through multiple SPs, by 10.1% to any SP handling the product, and 4.4% carve out their SP products
  - Specialty Pharmacy Ownership: 45.6% of SPs are PBM-owned, 38.2% are health plan-owned, 23.2% are independent, and 16.1% are hospital/IDN-owned
- The top diseases treated by Specialty Pharmaceuticals are shown in Figure 1

Figure 1: Diseases Treated by Specialty Pharmaceuticals

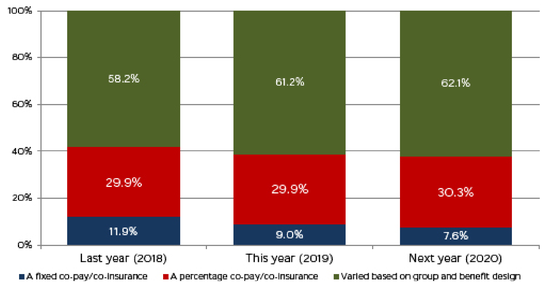


*Other included Orphan diseases, diabetes, and depends on distribution

- Plans covered clinician-administered products under the Medical Benefit (36.8%↓7.3%), 2.9% under the pharmacy benefit, the remainder used price and plan design to determine the benefit
- Specialty product co-pays continue to move from fixed to percentage with more plans using group and benefit design to determine the co-pay as shown in Figure 2

RESULTS CONTINUED

Figure 2: Co-Pay Types For Specialty Pharmacy Products



- Biosimilar use expected for all reference product indications 58.8% (↓7.3%), while 31.4% will restrict to approved indications (↓13.5%) and 9.8% will use indication as the basis for co-pay
- 10% (↓15%) of plans expect the biosimilar to be the only product available, co-pays are expected to be discounted off the innovator 58% (↓10.1%), and 32% (↓4.9%) to vary based on approval timing
- Expectations for member and prescriber education about biosimilars are shown in Figure 3
- Predicted savings from biosimilars are shown in Figure 4
- Challenges to the use of biosimilars are shown in Figure 5

Figure 3: Biosimilar Education

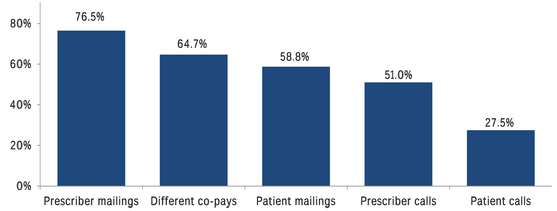
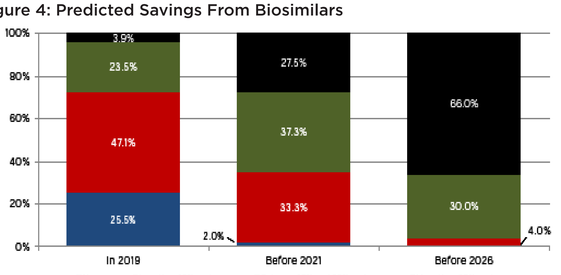
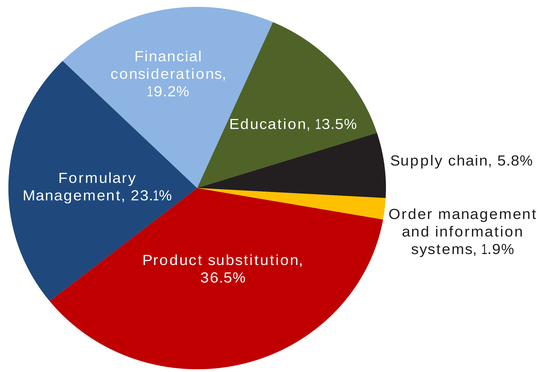


Figure 4: Predicted Savings From Biosimilars



RESULTS CONTINUED

Figure 5: Operational Challenges to Use of Biosimilars



CONCLUSIONS

- Health plans' expenditures associated with Specialty Pharmacies and Specialty Pharmaceutical products have shifted and are expected to grow with some relief coming from biosimilars.
- Medical and Pharmacy Directors, who commonly serve as P&T Committee members, have distinct opinions as to how to alter the process to adapt to evolving policies.
- Formulary management today is changing policies on benefit design, Specialty Pharmacy products, and biosimilars to achieve optimal patient coverage at a minimum cost.

REFERENCES

1 Long D. Pharmaceutical Trends, Issues, and Insights. Presentation for NASP (The National Association of Specialty Pharmacy). IQVia. September 24-26, 2018. Washington, DC

2 Mehr SR, Brook RA. Biosimilars in the USA: Will New Efforts to Spur Approvals and Access Spur Uptake and Cost Savings? *Pharmaceutical Medicine*, January 2019, 1-8.

Citation: Brook RA, Smeeding JE, Carlisle JA, Sax MJ. Management of Specialty Drugs, Specialty Pharmacies, and Biosimilars in the United States. *J Drug Assessment.* 2019. Available at www.TPG-NPRT.com

NASP ANNUAL MEETING & EXPO 2019 — PROMOTING PATIENT CARE, PHARMACY PRACTICE & POLICY

SPONSORSHIP: TPG-NPRT (National Payor Roundtable)

Contact Richard Brook 973-208-8621 Rich.Brook@TPG-NPRT or Rich@BH-WW.com for more information