COVERAGE AND REVIEWS OF MEDICAL DEVICES, LABORATORY, AND DIAGNOSTIC TESTING BY U.S. HEALTH PLANS

Richard A. Brook, MS, MBA[1,2]; Michael J. Sax, PharmD[1]; Jeff A. Carlisle, BA[1]; James E. Smeeding, RPh, MBA[1]
[1]TPG-National Payor Roundtable, Glastonbury, CT, USA, [2]Better Health Worldwide, Newfoundland, NJ, USA,

The 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.

BACKGROUND

- Medical devices and tests have the potential to save resources and they need to be approved by the health plan
- The US FDA defines a medical device as[1]:
  - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes
- Some tests allow the clinical team to identify diseases, and others identify markers to increase the potential effectiveness of therapies[2]
- A genetic test involves an analysis of human chromosomes, DNA, RNA, genes, and/or gene products (e.g., enzymes and other types of proteins), which is predominately used to detect mutations, genotypes, or phenotypes related to disease and health[3]
- Healthcare providers in the US market currently have available[4]:
  - More than 75,500 genetic testing products
  - More than 14,000 types of tests
  - 8-10 new testing products entering the market daily
  - A limited number (~200) of billing codes
- Health plans need to determine which devices and tests to approve and cover
- Based on recent programs with US payors, Medical Directors and sponsors, the authors decided to conduct a survey of medical and pharmacy directors involved with P&T Committees on their policies regarding genomic tests, genetic condition tests, disease markers tests, therapy response tests and their:
  - Involvement in coverage decisions
  - Requirements for medical device and test reviews
- Medical devices and tests have the potential to save resources and they need to be approved by the health plan
- Medical devices may facilitate the delivery of medicines or help regulate patient care
- Some tests allow the clinical team to identify diseases and others identify markers to enhance the likelihood of therapies being effective

OBJECTIVES

- To understand how U.S. health plans review and approve medical devices, lab and diagnostic tests
- To compare current results with prior surveys

METHODS

- An online, interactive survey was developed with 79 questions and included:
  - Yes / No questions
  - Lists for users to select single or multiple answers
  - Invitations to participate were sent to Medical and Pharmacy Directors working with US health plans, PBMs, and insurers from the TPG-NPRT database in November 2018
  - Material or financial incentives were not offered for completion of the survey
- Topics included:
  - Plan coverage and benefit design:
    - Geographical coverage
    - Types of lives with multiple member type information
  - Plan coverage of various types of tests, including:
    - Genomic tests
    - Genetic condition tests
    - Disease markers tests
    - Therapy response tests
  - Respondent involvement in coverage decisions
  - Requirements for dossiers and budget impact models for medical devices and various tests
- Survey responses were compared with prior surveys
- Survey invitations were received and reviewed by 662 managed care decision makers

RESULTS

- A total of 85 respondents (12.8% response rate) completed the survey, some questions were not answered by all respondents
- Many respondents reported multiple degrees, and the most common degree was MD (57%)
  - 42.9% were the senior officer, 13.1% regional, 8.3% payor specific, 1.2% therapeutic area specific. 36.9% worked for health plans, 13.1% PBMs, 9.5% IDNs, 2.4% PPOs/IPAs, 1.2% Government
  - 29.9% of plans were national, 24.7% were regional and 22.1% were local
  - The most commonly reported respondent titles were: Chief or Senior Officer (43%), Payor specific (19%), Regional (8.9%), or therapeutic area specific (1.3%)
- Plans could cover multiple member types:
  - Commercial (58.6%=FFS, 77.8%=HMO/PPO)
  - Medicaid (Traditional=27.8%, HMO/PPO=72.3%)
  - Medicare (71%, PDP-only=51%)
  - Employer/Self-funded=79%
  - IDN (43.6%, 340B Qualified=43.8%)
- For medical devices and tests:
  - Involvement in coverage decisions are shown in Figure 1
  - Requirements for dossiers and budget impact models (BIMs) are shown in Figure 2
  - Dossiers were not required in 66.7% of device reviews and 67% of tests
- Medical devices were considered non-experimental if:
  - Listed in a compendia=37.9%
  - More than 2 Randomized Clinical Trials (RCTs)=29.3%
  - Listed in a guideline=17.2%
  - Listed in 2 or more compendia=15.5%

RESULTS CONTINUED

- For plans that required (or used) Budget Impact Models:
  - 38.7% were developed internally, down 3.6% from last year
  - 54.8% were developed with assistance from the manufacturer, down 2.9% from last year
  - 6.5% used the models provided by manufacturers
- Genomic tests for certain types of conditions are shown in Figure 3
  - Compared with last year, coverage for Cardiovascular tests decreased by 12.4%, while the other categories increased: OB/GYN tests by 7.1%, other tests increased by 2.6% and Oncology by 0.6%
- Figure 4 shows the coverage of tests for Genetic Conditions
  - Disease marker tests were covered in all cases by 78.3%↓6.9% or if under a threshold by 15%↑4.6%
  - Therapy response tests were covered in all cases by 69.5%↑3.7%, and if under a threshold by 20.3%
- Involvement in decisions for medical devices (All=63.3%, some=50.7%), genetic tests (All=31.4%, some=45.7%) and diagnostic tests (All=31.4%, some=45.7%)

Figure 1: Respondent Involvement in Coverage Decisions

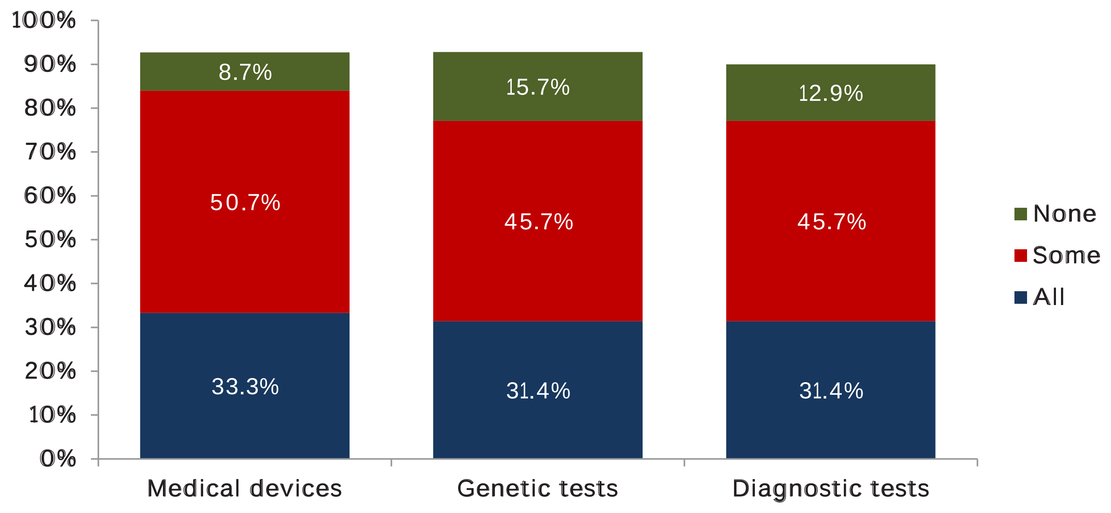


Figure 2: Requirements for Dossiers and Budget Impact Models (BIMs)

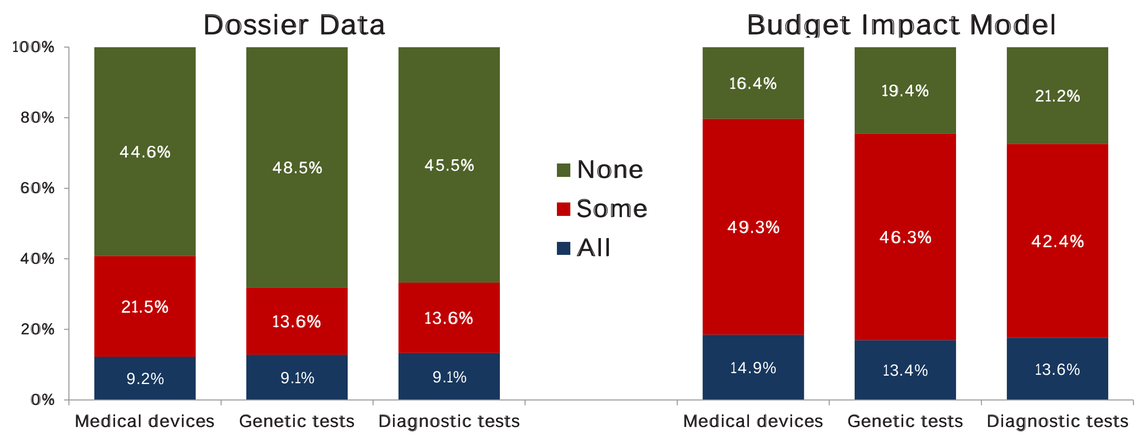


Figure 3: Genomic Test Coverage

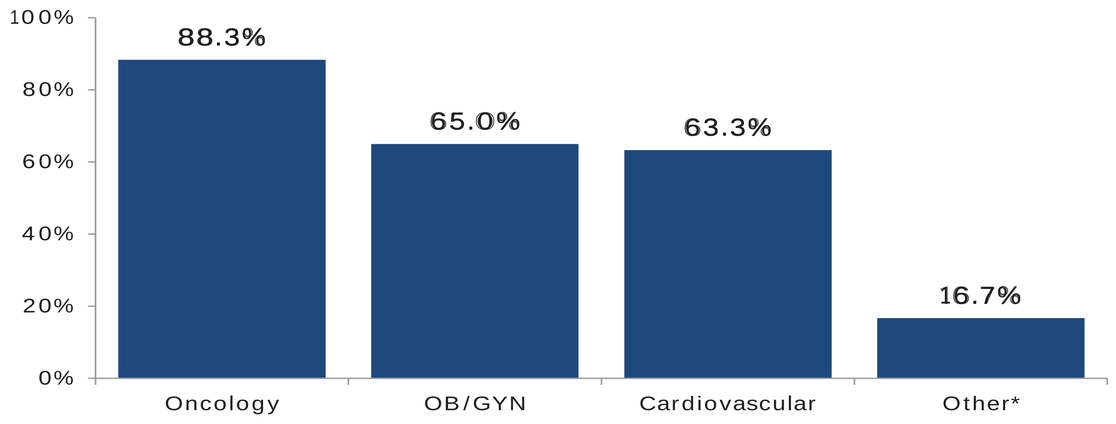
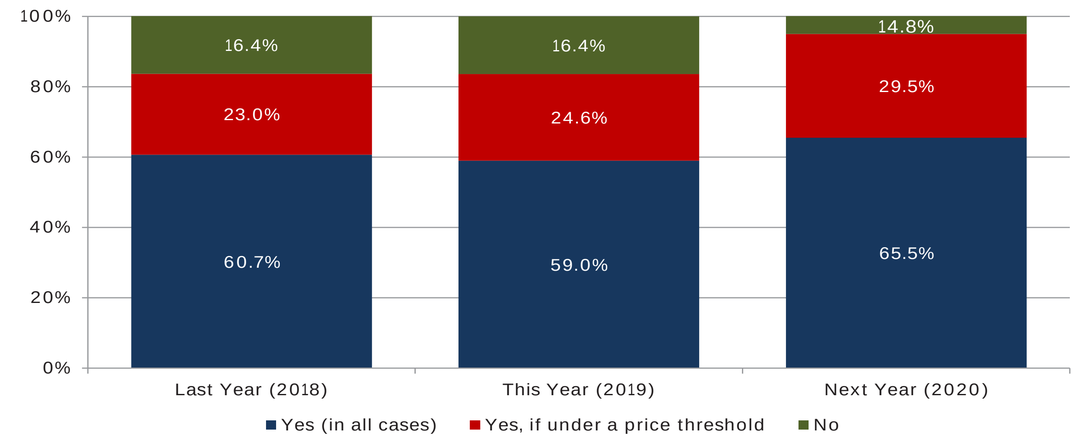


Figure 4: Plan Coverage of Genetic Condition Tests



CONCLUSIONS

- The managed care decision-making process goes beyond pharmaceuticals and is undergoing a series of changes
- Medical and pharmacy directors, who commonly regulate utilization, have distinct opinions as to how to manage their plan's expenditures and outcomes
- Medical devices are often reviewed by the same committees that review pharmaceuticals
- Health plan management of tests is challenged by the different types of tests, the large number of tests available, and the limited billing codes in current use
- Health plan management today is changing policies on medical devices and testing coverage and reviewing requirements in hopes of achieving optimal patient coverage at a minimum cost

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