Coverage and Reviews of Medical Devices, Genomic and Diagnostic Testing by US Health Plans

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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[4]
- Healthcare providers in the US market currently have available[5]:
  - 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

OBJECTIVE

- To understand how US health plans review and approve medical devices, lab and diagnostic tests
- The survey focused on medical device and test:
  - Review requirements for dossiers and budget impact models
  - Coverage

METHODS

- An online, interactive survey was developed with 69 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 2017
  - 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 247 managed care decision makers

RESULTS

- A total of 77 respondents (31.2% 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%)
  - 40.5% worked for health plans, 11.4% PBMs, 8.9% Integrated Delivery Networks (IDNs), 3.8% for Preferred Prescriber Organizations (PPOs) / Independent Provider Associations (IPAs), 1.3% for the Government, the remainder consultants
  - 39.2% of plans were national, 27.5% were regional and 33.3% were local
  - The most commonly reported respondent titles were: Chief / Senior Officer (43%), Payor specific (19%), Regional (8.9%), or therapeutic area specific (1.3%)
- Plans cover multiple types of members: commercial (68.8%=FFS,76.5%=HMO/PPO), Medicaid (Traditional=36.4%, HMO/PPO=67.9%), Medicare (71.2%,PDP-only=50%), Employer/Self-funded=77.1% and IDN (47.7%, 340B Qualified=43.5%)
- In their reviews, plans compare medical devices with: other standards of care (64%), other medical devices only (23%) or pharmaceuticals (13%)
- 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
- For plans that required (or used) Budget Impact Models:
  - 42.3% were developed internally
  - The remaining 57.7% developed with assistance from the manufacturer
- Only 37.5% of plans required test ordering through an Electronic Medical Record (EMR) system
- Genomic test for certain types of conditions are shown in Figure 3
- Figure 4 shows coverage was similar for conditions with:
  - Disease markers (ie, BRCA in breast cancer, RA testing, etc) (Yes/No = 71.4%/8.9%)
  - Known therapy responses (ie, HCV, RA, etc.,) (Yes/No = 73.2%/7.1%)

RESULTS CONTINUED

Figure 1: Respondent Involvement in Coverage Decisions

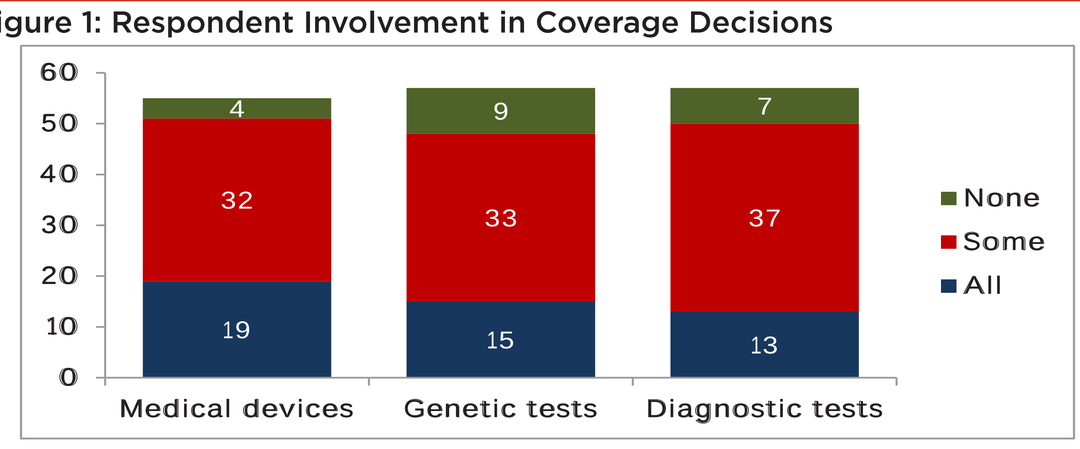


Figure 2: Requirements for Dossiers and Budget Impact Models (BIMs)

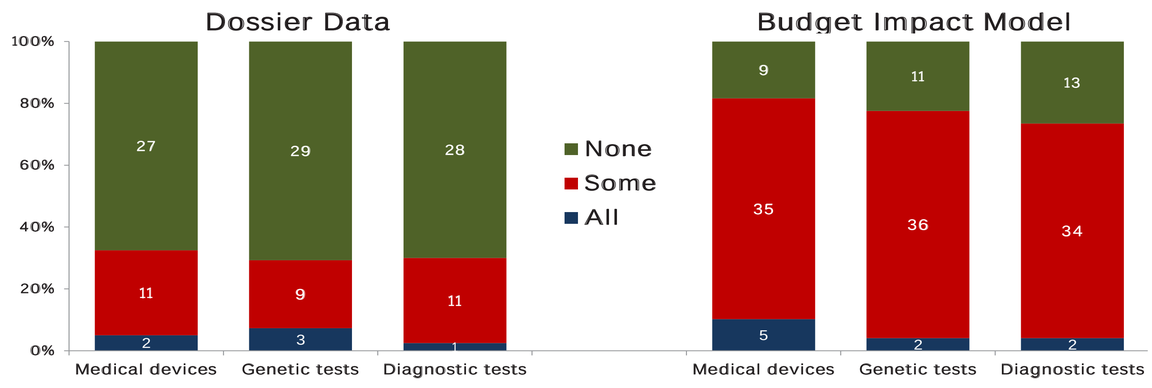
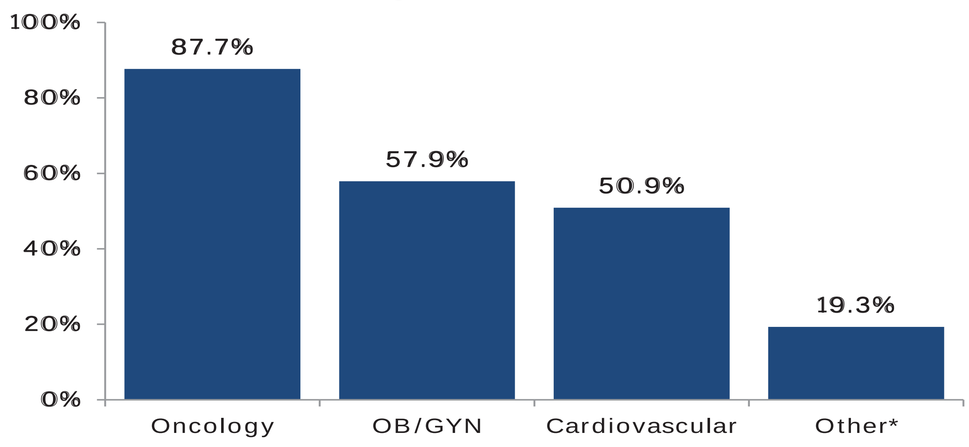
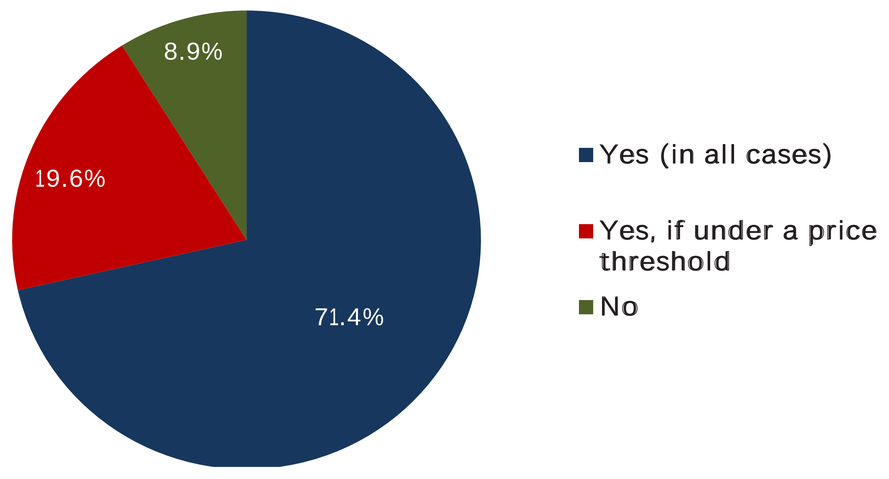


Figure 3: Genomic Test Coverage



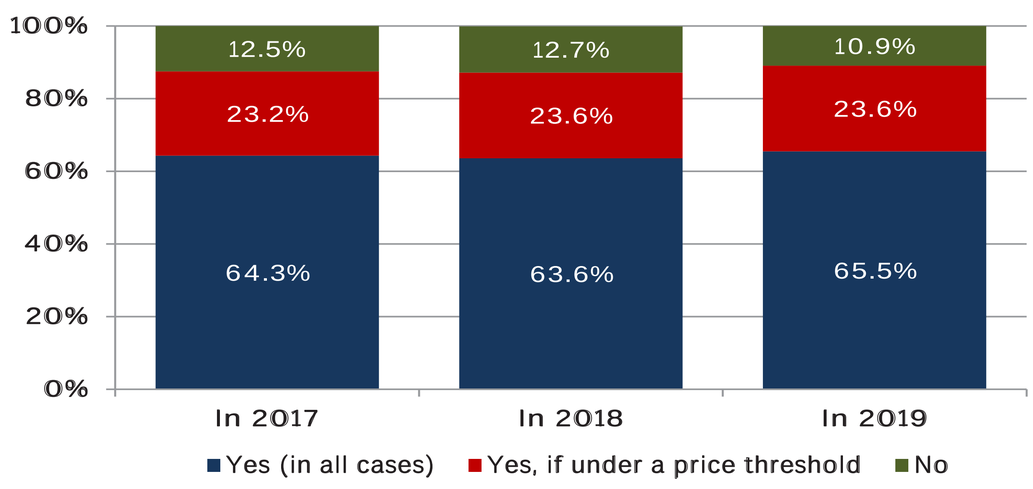
* Other included HCV/RA, Psychiatric drugs, Specialty Pharmaceuticals, Gastrointestinal, Cystic Fibrosis, those proven to have clinical validity and clinical utility

Figure 4: Plan Coverage of Disease Marker and Therapy Response Tests



- Plan coverage of tests for genetic conditions was high, and is expected to increase as shown in Figure 5

Figure 5: Plan Coverage of Genetic Condition Tests



CONCLUSIONS

- The managed care P&T Committee decision-making process is undergoing a series of changes
- Medical devices are often reviewed by the same committees that review pharmaceuticals
- Health plan management of tests are 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 review requirements in hopes of achieving optimal patient coverage at a minimum cost

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