BACKGROUND

- Medical devices and tests have the potential to save resources and they should be approved by the health plan.
- The US FDA defines a medical device as:
  - 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 International Dictionary of the Pharmaceutical Industry, or the United States Pharmacopeia, 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 humans or animals, or
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended uses by chemical interaction or 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 principal intended purposes.
- Some tests allow the clinical team to identify diseases, and others identify markers to increase the potential effectiveness of therapies.
- 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 diseases and health.
- Healthcare providers in the US market currently have available:
  - more than 80,000 medical device products
  - more than 14,000 types of tests
- The survey focused on medical device and test:
  - Review requirements for dosiers and budget impact models
  - Coverage

OBJECTIVE

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

METHODS

- An online, interactive survey was developed with 63 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-NPR database 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 dosiers 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 73 respondents (51.2% 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 Health Plans.
  - 33.3% were local
  - The most commonly reported respondent titles were: Chief Medical Officer and Chief Pharmacy Officers in 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.
  - The Pharmacy Group provides consulting services to the healthcare and laboratory industries.

CONCLUSIONS

- The managed care P&T Committee decision-making process is undergoing a series of changes.
- Medical devices are 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 in hopes of achieving optimal patient coverage at a minimum cost.

REFERENCES

- Brook RA, Carlisle JA, Smeeding JE. Coverage and Reviews of Medical Devices, Genomic and Diagnostic Testing by US Health Plans. Value Health 2018;21(Suppl1)
- Zuckerman BH, Cawley J. Health benefits and the growth of new medical tests: evidence from the development of BRCA testing. Value Health 2018;21(Suppl1)

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