CHALLENGES WITH SPECIALIZED TESTING

FLASCO
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Objectives

At the conclusion of this session, attendees will be able to…

- Discuss the current landscape and growth in specialized testing
- Describe the challenges associated with coverage, coding and reimbursement of specialized testing
- Recognize the challenges and burdens associated with prior authorization demands for specialized testing

Precision Medicine

"A form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease. In cancer, precision medicine uses specific information about a person's tumor to help diagnose, plan treatment, find out how well treatment is working, or make a prognosis. Examples of precision medicine include using targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose cancer. Also called personalized medicine. "

NCI Dictionary of Cancer Terms

Goal of personalized medicine, "the right patient, with the right drug, at the right dose at the right time"

www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine

Molecular Diagnostics and Genomic Testing in Cancer

- These tests can guide decision making in treatment pathways for certain cancers and may help:
  - Avoid unnecessary or ineffective therapies
  - Adjust dosages to avoid toxicity and improve efficacy
  - Identify treatments the patient's cancer is more likely to respond to
- Drug coverage may be dependent on favorable diagnostic results

National Institute of Health - Precision Medicine: From Science to Value
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5989714/

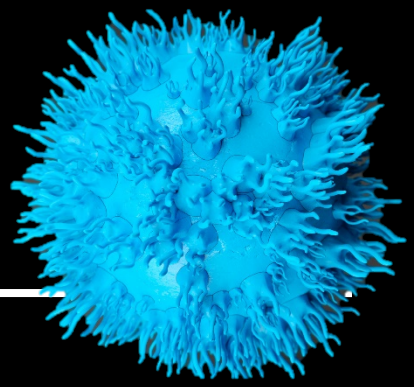
Complementary vs. Companion Diagnostics

- Complementary Diagnostics - associated with a class of drugs and are not limited to specific uses in the labels

- Companion Diagnostics (CDx) - typically linked to a specific drug within its approved label .
  - Example of label language under Indications and Usage: "*Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza" **

* www.accessdata.fda.gov/drugsatfda_docs/label/2018/208558s006lbl.pdf

Growth in Specialized Testing



- Approximately 1 in 4 drugs approved by the FDA over the past 4 years was a personalized medication, with the label including a reference to a specific biological marker that could be identified by diagnostic tools to help guide treatment decisions.
- The FDA approved a record 16 new drugs with companion diagnostic tests in 2017, accounting for nearly 35% of new molecular entities approved.
- More than 1,100 oncology agents are in various stages of pipeline development according to the industry organization PhRMA.
- Most (73%) oncology agents are being developed inclusive of biomarkers

Source: Clinical Leader – Companion Diagnostics and the Future of Oncology Clinical Trial Design

Challenges – Coverage & Reimbursement

- FDA cleared or approved companion diagnostics required for the use of a drug are seen to have proven clinic utility and are more likely to be covered
  - Still, payers may require the test to cover the drug – but not cover the test
- Advanced lab tests, such as molecular diagnostic (MolDx) tests may be covered under the CMS MolDx program that aligns coding and reimbursement across participating local MACs.
  - Variability remains among nonparticipating MAC jurisdictions.

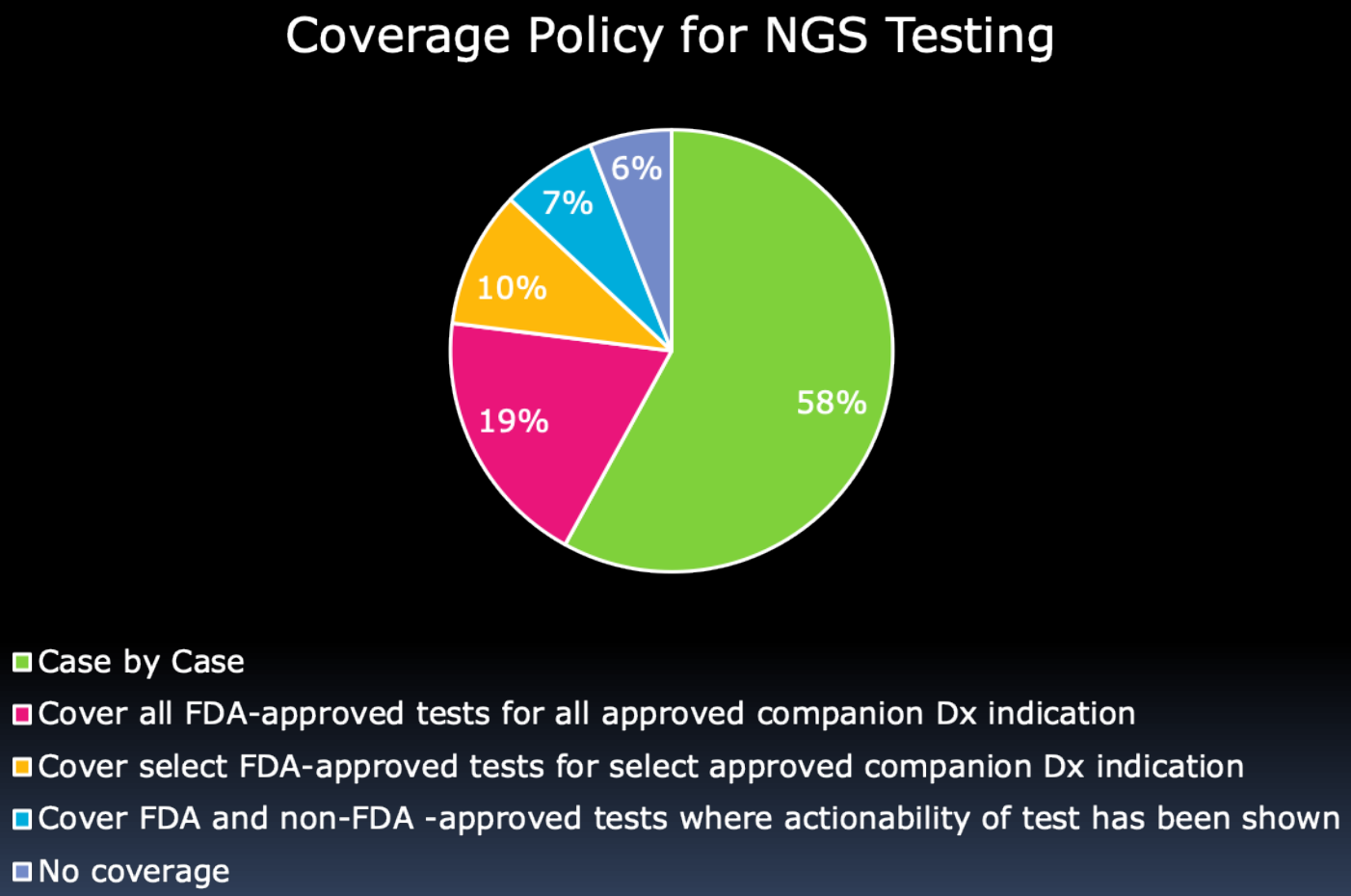
Challenges – Coverage & Reimbursement

- Test may be recommended by guidelines, but
  - Test is not covered by the payer
  - Patient's out-of-pocket costs are prohibitive
- Test may not have a specific CPT code
- Payers may require test is done in their contracted lab
  - Providers may not have updated list of:
    - Payer's preferred laboratory for each test
    - List of tests performed by laboratory

Next Generation Sequencing (NGS) Medicare NCD

- CMS has deemed NGS diagnostic tests to be reasonable and necessary, and the agency reimburses them as long as they are performed in a CLIA-certified laboratory and meet the following requirements:
  - The patient has recurrent, relapsed, refractory, metastatic, or advanced of cancer.
  - The same next-generation sequencing test has not been used previously for the same primary diagnosis.
  - The patient has decided to seek further treatment such as chemotherapy.
  - The next-generation sequencing test has FDA approval as a companion in vitro diagnostic, as well as approval for that patient's cancer.
- Determinations of coverage for laboratory-developed tests that have not been FDA-approved or cleared will be up to the local MACs
- NCD as written would result in NGS testing to be non-covered for Medicare beneficiaries with early-stage cancer

In a 2018 survey, 97 Managed Care Organization (MCO) representatives reported on how they determine coverage for NGS testing



Source: The 2019 Genentech Oncology Trend Report
www.genentech-forum.com/trend-reports.html

Laboratory Benefit Managers (LBMs)

- Commercial payers are turning to laboratory benefit managers (LBMs) to navigate the rapidly evolving, complex and costly molecular/genomic testing landscape through services including;
  - Medical policy administration services
  - Decision support tools
  - Lab test formularies
    - Lab tiers
  - Prior authorization
  - Network of preferred laboratories
- A 2018 Avalere survey found that 14% of payers have implemented third-party LBM, and an additional 30% are actively exploring it.

Laboratory Benefit Managers (LBMs)

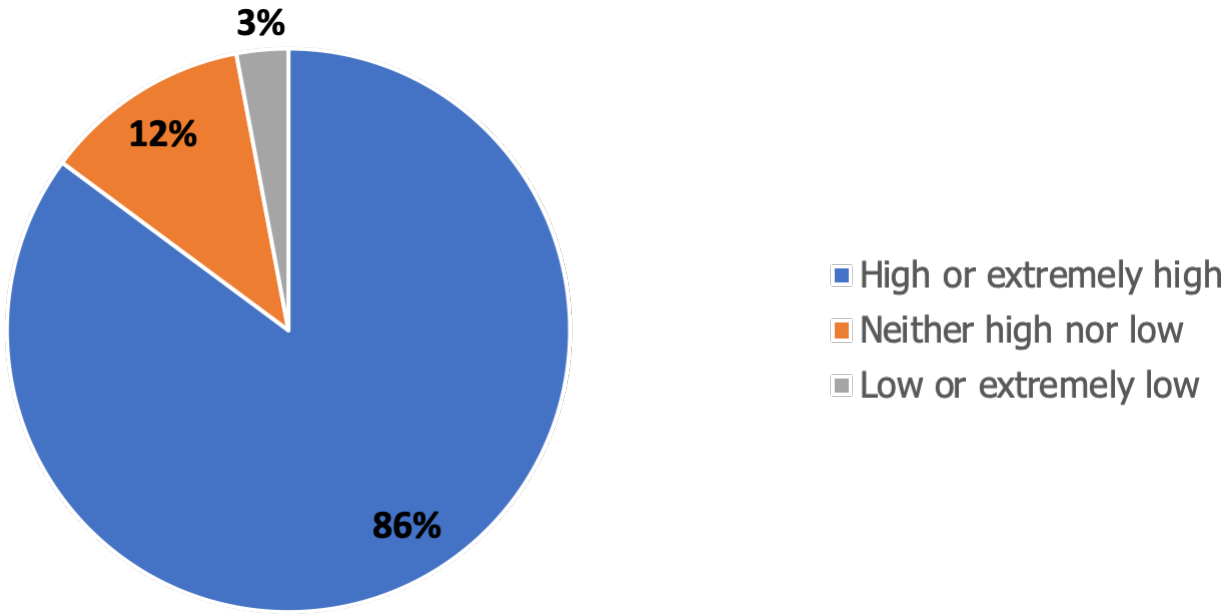
- LBMs include:
  - Avalon
  - Beacon
  - eviCore
- Challenges with LBMs
  - Ordering provider limited to approved laboratories – disrupting established clinical relationships between physicians and their preferred labs
  - Cumbersome and varying internal protocols and processes
  - Delays in patient treatment
  - Advance notification and prior authorization likely to be required
  - Need to identify where specific tests can be performed
  - Lab "formularies" may differ from 1 LBM to another
  - LBMs are disconnected from the patient

Challenges – Prior Authorization (PA)

- Private payers are increasingly requiring the use of PA for molecular/genomic testing
  - May affect appropriate access to tests if PA requirements and guidelines are not updated promptly when new evidence and clinical guidelines are released
  - Substantial variation is likely to exist between payers coverage decisions
- Labs are moving away from "retroactive authorization" as more payers are now requiring prior authorization to be completed by the ordering physician
  - Delays in testing may compromise specimen stability
- Providers often don't have access to
  - Up-to-date lists of laboratories that are on the payers (or LBMs) preferred list, or
  - Tests the laboratory is allowed to run for that payer
- Ordering providers have the administrative burden and cost of the PA process with no associated reimbursement for those costs

Physician perspective on PA burdens

Q. How would you describe the burden associated with PA in your practice?



Source: American Medical Association - 2018 Prior Authorization Survey – Figures have been rounded

Develop Manual to Facilitate Approval Process

- Develop and maintain a list of clinical practice guidelines for the tests.
- Develop and maintain database of approved laboratories and molecular/genomic tests they perform (for each payer).
- Include the known procedures and requirements for each insurance payer or LBM, indexed by company.
- Maintain a list of tests requiring pre-notification or prior authorization. Outline of process and steps to obtain the required approval or authorization number (for each payer/LBM).
- Determine the standard information needed for each request.
- Create a standard form for staff member to utilize for recording interactions with the insurance companies and lab benefit management organizations.