Navigating Medical Necessity in Three Acts

Medical Necessity Webinar Series Part 1

Define and Discuss the Use of Evidence to Form Medical Necessity Criteria and Policy

April 25, 2022

Catalyst Center Funding Acknowledgement
The Catalyst Center (Grant U1TMC31757) is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $500,000, with no financing by nongovernmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS or the U.S. Government.

National Coordinating Center for the Regional Genetics Networks Funding Acknowledgment
This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under Cooperative Agreement #UH9MC30770 from 6/2020-5/2024 for $800,000 per award year. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

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Educational CME Information

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Financial Disclosure & Mitigation

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All relevant financial relationships listed have been mitigated.

Name	Program Committee Member	Presenter Panelist Moderator	Peer Reviewer	Financial Disclosure Relationship/Company
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Caisse, Molly	X			Nothing to disclose
Comeau, Meg	X			Nothing to disclose
Ginsburg, Susanna	X			Nothing to disclose
Guysi, Nicole	X	X		Nothing to disclose
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Learning Objectives

At the conclusion of this activity, participants should be able to:

- Define what is medical necessity.
- Describe how evidence is evaluated to determine whether a test or service is deemed medically necessary.
- Explain how the evaluation of benefits and costs to families and to payers are considered when determining medical necessity policy.

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Three webinars with cases

- Webinar 1 - Medical necessity definition and use of evidence to create policy
- Webinar 2- Medicaid and EPSDT and collaborative agreements (the Title V and Medicaid relationship); Introduction to the practical application of medical necessity
- Webinar 3- The practical application of medical necessity (continued)
  - Understanding payer authorization processes
  - Requesting authorization
  - Denials and appeals

Our team of presenters

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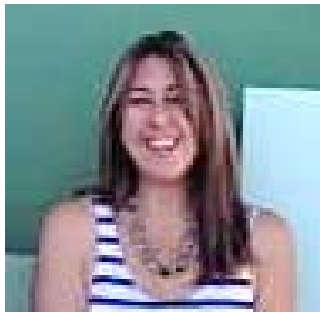

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Medical necessity definition and use of evidence to create policy

Goals

- Understand how evidence is evaluated to determine if / when / under what circumstances a test or service is deemed medically necessary.
- Understand who is making the determination and the process that is being used

A definition

"Medically necessary services are health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine."

https://www.healthcare.gov/glossary/medically-necessary/

National Association of Insurance Commissioners

https://content.naic.org/sites/default/files/consumer-health-insurance-what-is-medical-necessity.pdf

Parts of this definition include

- Purpose (and evidence of)
- Mechanisms to provide the service

Purpose

- To prevent, diagnose, and treat medical conditions
  - Treatment includes curative care, ameliorate pain and suffering, and care that is designed to rehabilitate to the highest level possible
  - Physical and Mental health

Evidence of Purpose

- Most states – “prevailing” or “generally accepted” definition of evidence
  - In statute
  - In rule
- A few states- incorporate “evidence-based standards”
  - States utilize a variety of sources to get this information
    - Cochrane
    - Institute for Clinical and Economic Review (ICER)
    - MED
    - The National Institute for Health and Care Excellence (NICE)
  - Quality of the evidence
  - States can use
    - Medical directors
    - Technology assessment committees for guidance
    - Vendors
    - Managed care

Evaluation of Evidence by States

- Quality of Care
  - Use of Evidence
    - Consideration will be given to available scientific evidence, professional standards, expert opinions, safety, and clinical effectiveness.
    - Decisions are flexible to permit exceptions and take clinical circumstances, improvements in care and changes in literature into consideration.
    - Consensus among the medical community can be used and play a role when no definitive evidence exists or evidence is insufficient at the present time.

  - Health care services and technology must improve the net health outcome.
    - A recommendation necessitates good evidence that the procedure is effective in reducing morbidity and mortality: medical benefits must outweigh risks.
    - Services must be as beneficial as any established alternative and improvement must be attainable outside the investigational setting.

https://mn.gov/dhs/partners-and-providers/news-initiatives-reports-workgroups/minnesota-health-care-programs/health-services-council/

Evaluation of Evidence by States (continued)

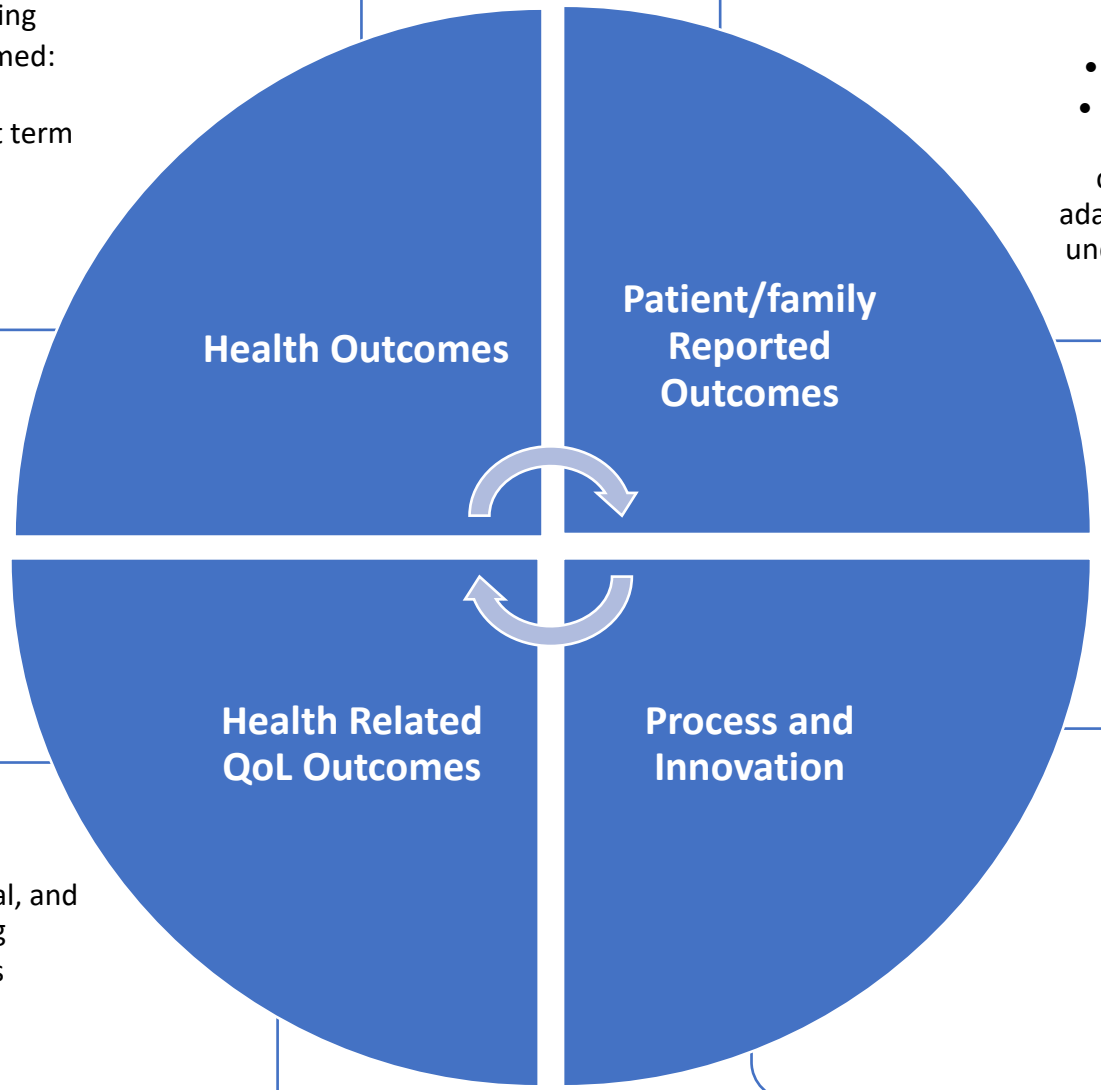
- Value of Care
  - Reasoned and defensible coverage decisions are essential for a fairer and more efficient health care system.
  - Cost-effectiveness will guide decision-making.

    Cost-effective services and technologies are considered to be:
    - At least as effective and less costly than alternatives.
    - More effective and more costly than alternatives, but resultant patient outcomes justify additional expenditure.
    - Less effective and less costly than alternatives, but resultant patient outcomes from the use of more expensive alternatives *do not* justify additional expenditures.

Benefits

- Change to medical management
- Medical decision making
- May be disease-informed: OS/PFS vs. HbA1c
- Often measured short term

- Satisfaction
- Ending odyssey
- Changes in family dynamics
- Changes in control, distress, stigmatization, labeling, risk comprehension, knowledge, adaptation, self-esteem, worry, understanding and acceptance



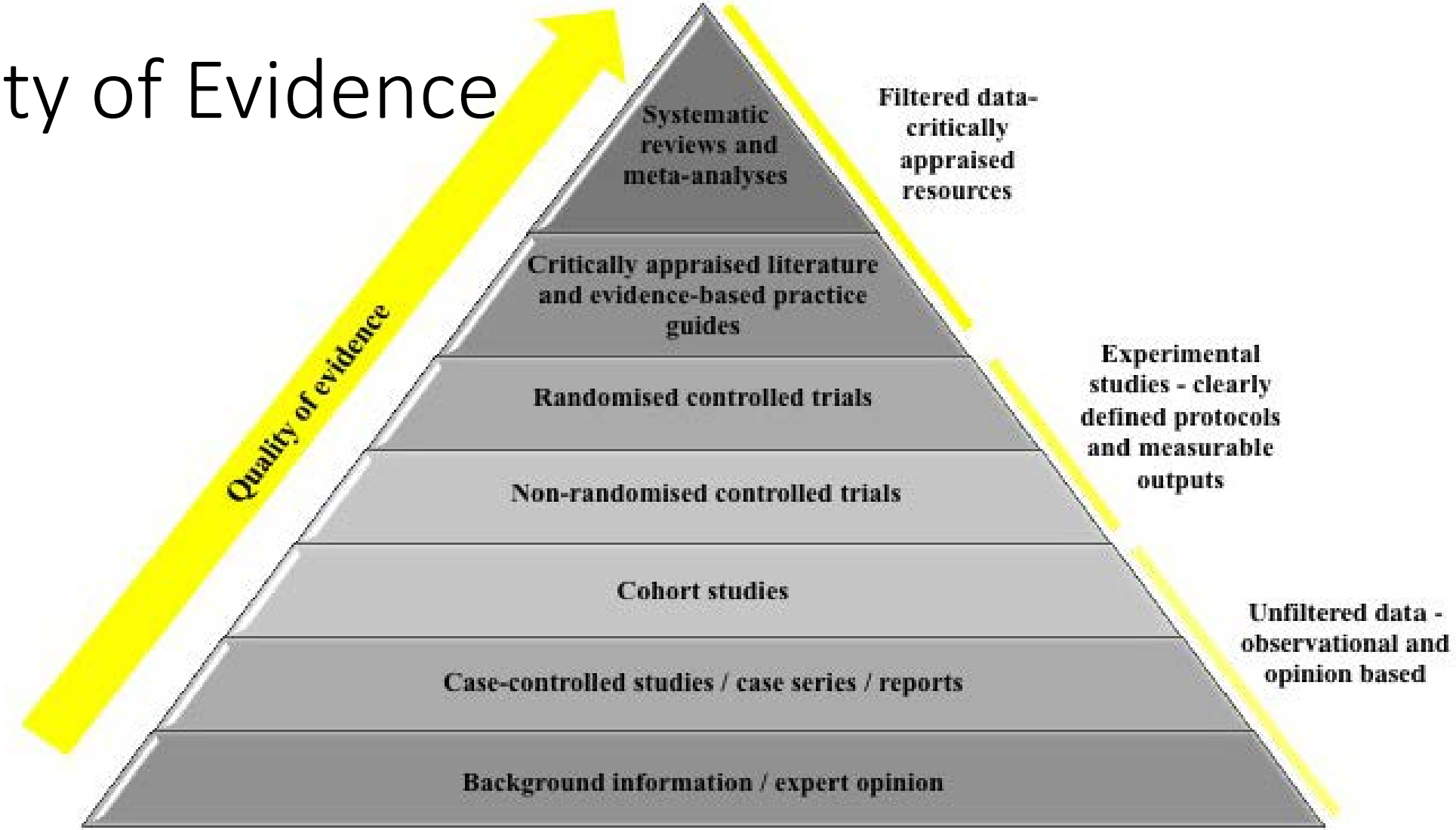
- Physical, mental, social, and emotional functioning
- Standard assessments exist, but may also be disease informed

- Care interactions
- Access
- Administrative Burden
- Quality assurance
- Research
- Discovery

Costs

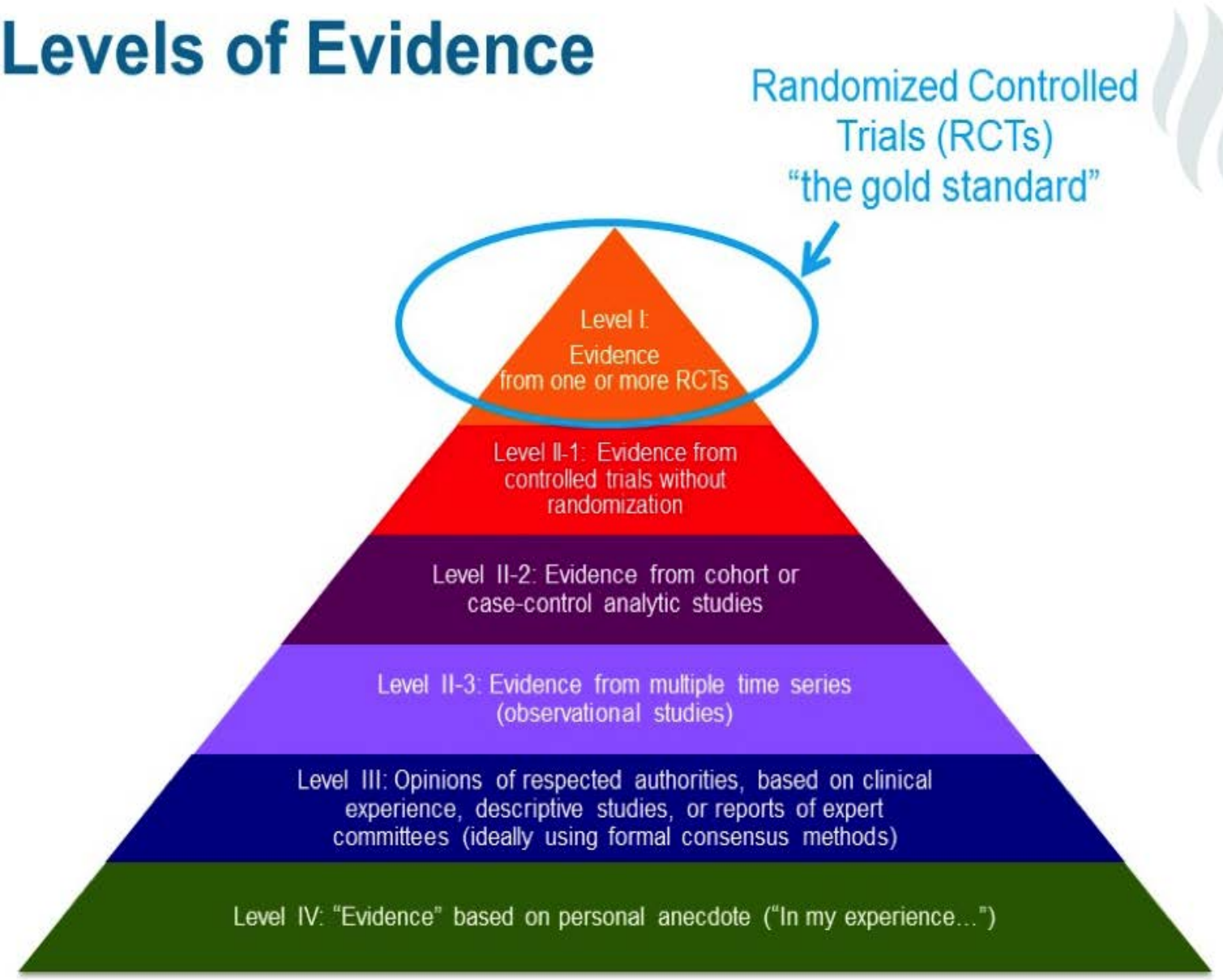
- Cost of testing
- Cost of downstream services rendered or avoided
- Cost of healthcare utilization
- Indirect costs of transport, medical food and devices
- Lost wages/productivity

Quality of Evidence



https://crcaustralia.com/media-releases/from-evidence-based-medicine-to-value-based-healthcare-is-australia-ready/

Levels of Evidence



https://www.healthcatalyst.com/5-reasons-practice-evidence-based-medicine-is-hot-topic

Strength of evidence: Principal domains

- *Risk of bias*
- *Consistency*
- *Directness*
- *Precision*
- *Publication bias*

Guyatt GH, Oxman AD, Vist GE, et al. (2008). GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ,336(7650):924-6.

https://effectivehealthcare.ahrq.gov/products/methods-guidance-tests-grading/methods

Quality of evidence

- Strength of evidence grades and definitions Grade Definition used by AHRQ Evidence-based Practice Centers
  - High We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
  - Moderate We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
  - Low We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
  - Insufficient We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/methods-guidance-grading-evidence_methods.pdf

Mechanism to provide the service

- Type – what services
- Scope – by whom
- Frequency – how often
- Duration – how much
- Site – where can they be provided

The family perspective

- Have you known that these processes exist?
- Have you participated?
- Have you been heard?
- How would you like this process to change?

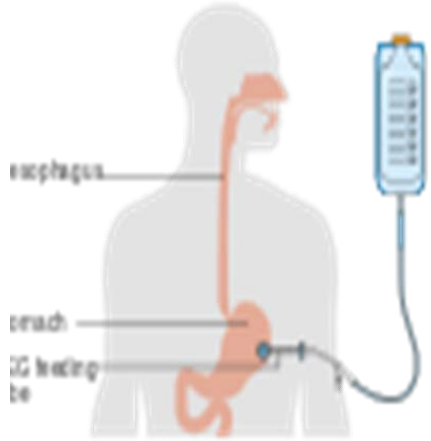
Therapeutic Case

- Adolescent male with Phenylketonuria (PKU)
- Prescribed Phenex-2 (17 cans/month, $1057)
- Insured by a self-funded employer insurance plan
- Medical Food coverage exclusion

Medical Food is formulated to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition.

https://www.fda.gov/Food/GuidanceRegulation//MedicalFoods

BARRIERS TO MEDICAL FOOD ACCESS



Therapeutic Case Policy Considerations

- Conducted a benefits investigation with insurance company
- How/ why medical foods are excluded in health insurance

Case to be continued - Authorization process, next session

Diagnostic Case

- 5yo male global developmental delay and autism.
- History of 3 seizures (one at age 3, two at age 5)
- PCP ordered Fragile X which was negative
- Has had frequent respiratory infections requiring hospitalization subsequently found to have immune deficiency
- Family history of autism and varying developmental delays (in 2 maternal male cousins and a maternal uncle) and unexplained recurrent pregnancy loss for parents.
- Seen in Medical Genetics where chromosomal microarray (CMA) was normal
- Medical Genetics is now recommending whole exome sequencing (WES)

Addressing Policy Coverage Criteria (when available)

- WES results will directly impact clinical decision-making and/or clinical outcome*
- A genetic etiology is the most likely explanation for the phenotype*
- No other causative circumstances (e.g. environmental exposures, injury, infection) can explain symptoms*
- Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing is available
- The differential diagnosis list and/or phenotype warrant testing of multiple genes
- If a diagnosis is made [treatment/testing/medication] will be performed/stopped. If a diagnosis is not made, then [treatment/testing/medication] will be performed/stopped.
- There are multiple anomalies affecting multiple organ systems and there is a family history of [relevant symptom].
- Appropriate evaluations for non-genetic causes were performed and negative.
- There is no specific syndrome fitting the presentation.
- Multiple genes are warranted and WES is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis

Discussion – family and provider perspectives

- What works in this policy process?
  - Is it sufficiently transparent?
  - Is it happening in too many places?
  - When are criteria too vague to be useful?
- What is the best case for being involved in the development of criteria?
- How and when should value (quality/cost) be considered?

Webinar #2

- May 20, 2022, 1 pm ET
- Medicaid and EPSDT and collaborative agreements (the Title V and Medicaid relationship)
- Introduction to the practical application of Medical Necessity

Webinar #3

June 2022

- The practical application of Medical Necessity
  - Understanding payer authorization processes
  - Requesting authorization

Thank you!