Navigating Medical Necessity in Three Acts

Three webinars with cases

- Medical Necessity definition and use of evidence to create policy
- Medicaid and EPSDT and collaborative agreements (the Title V and Medicaid relationship)
- The practical application of Medical Necessity –
  - Understanding payer authorization processes
  - Requesting authorization
  - Denials and appeals

Medicaid and Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)-
The Title V and Medicaid Relationship
Initial Prior Authorization Request

May 20, 2022

Delicate Arch- Arches National Park or chromosomal banding in the desert?

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Educational CME Information

ACMG Education
acmgeducation.net

Financial Disclosure & Mitigation

ACMG
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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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Learning Objectives

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

1. Explain how EPSDT sets a standard for care for children and youth and its relationship to medical necessity
2. Compare the relationship of Title V and Medicaid for supporting coverage and access to services in states.
3. Define the first steps in the process of getting prior authorization for medically necessary services

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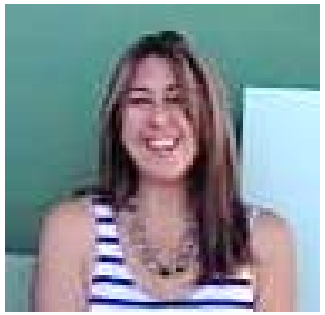

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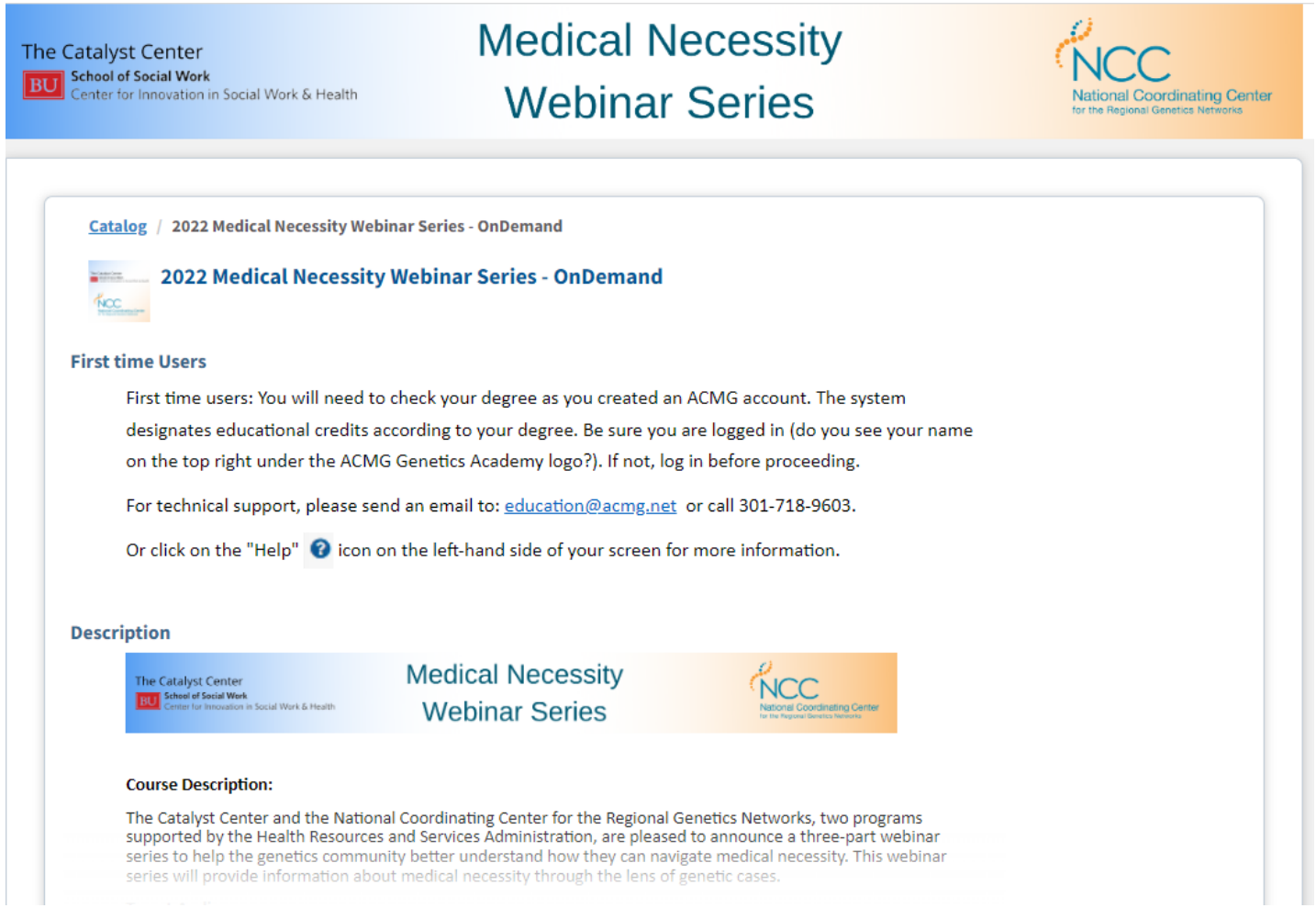
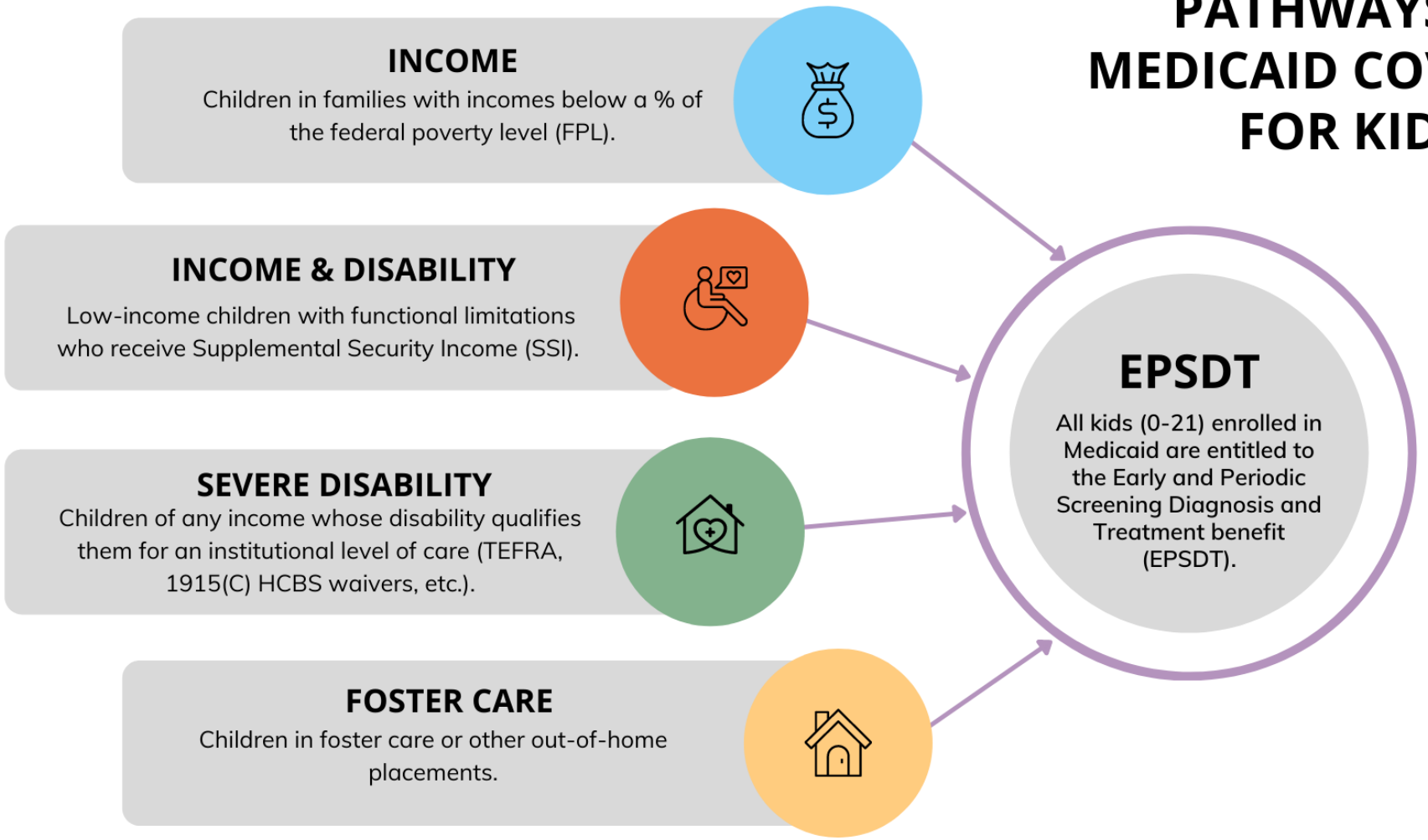


EPSDT and Title V

- Medicaid as secondary coverage for children with disabilities (TEFRA)
- EPSDT
  - Definition of services that must be covered
  - Taking apart the definition
  - Cases/ case law on EPSDT
- Title V ability to inform Medicaid
  - Formal agreement language
  - Practical application
  - Perspectives from MCH (outcome driven) and Medicaid (coverage driven)

PATHWAYS TO MEDICAID COVERAGE FOR KIDS



EPSDT

- The establishment of the EPSDT standards in 1967 created a more comprehensive set of benefits that supersede other state or federal statutory limitations.

- Per CMS guidance, “The goal of EPSDT is to assure that individual children get the health care they need when they need it – the right care to the right child at the right time in the right setting.”

https://mchb.hrsa.gov/maternal-child-health-initiatives/mchb-programs/early-periodic-screening-diagnosis-and-treatment

EPSDT - Definition

The EPSDT definition of medical necessity recognizes the importance of providing services to enhance and address the dynamic nature of child development. Services must support a child's optimal development .

"The state should also consider all aspects of a child's needs, including nutritional, social development, and mental health and substance use disorders. States are permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases, but those parameters may not contradict or be more restrictive than the federal statutory requirement."

http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html

EPSDT

When	**E**arly	Assess and identify problems as early as possible
	Periodic	Check children's health status at regular, periodic, age-appropriate intervals
What	**S**creening	Provide physical, mental, developmental, dental, hearing, vision, and other screening tests to detect potential problems
	Diagnostic (aka Diagnosis)	Perform diagnostic tests to follow up (rule out or confirm) when screening identifies a risk or potential problem
	Treatment	Control, correct or reduce health problems found

EPSDT – Specific services covered

- Provision of medically necessary screening and preventative care including
  - Comprehensive health and developmental history
  - Comprehensive physical exam
  - Appropriate immunizations (according to the Advisory Committee on Immunization Practices)
  - Laboratory tests (including lead toxicity screening)
  - Health Education (anticipatory guidance including child development, healthy lifestyles, and accident and disease prevention)

EPSDT – Specific services covered (cont.)

- Enabling services that support a child's ability to get medically necessary services.
  - Services such as transportation and services provided outside of a state's boundaries are included in here.

EPSDT – Access to services

- Minimal or limited cost sharing for children and their families so that these costs do not become a barrier to access to services.
- Assurance of adequacy of provider access. This has been interpreted to include the need for adequate payment for services to assure access.

EPSDT – Applying the definition - process

Medical necessity determinations under EPSDT must be made on a case-by-case basis. While parameters can be set for prior authorization, a hard stop policy to absolutely limit services cannot be created for children covered under EPSDT. Screenings cannot be part of a prior authorization process. (emphasis ours)

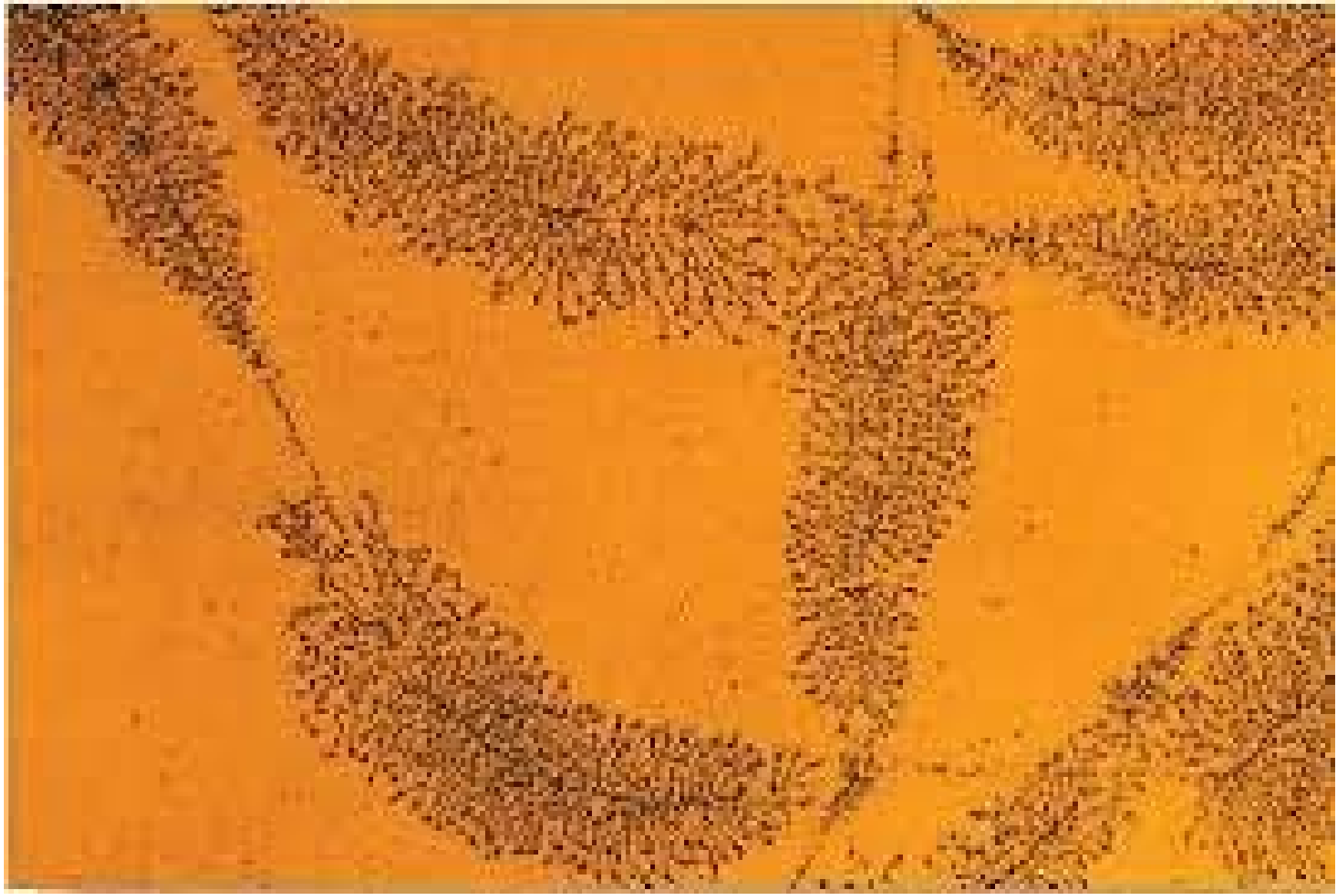
http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html

Title V's ability to influence Medicaid

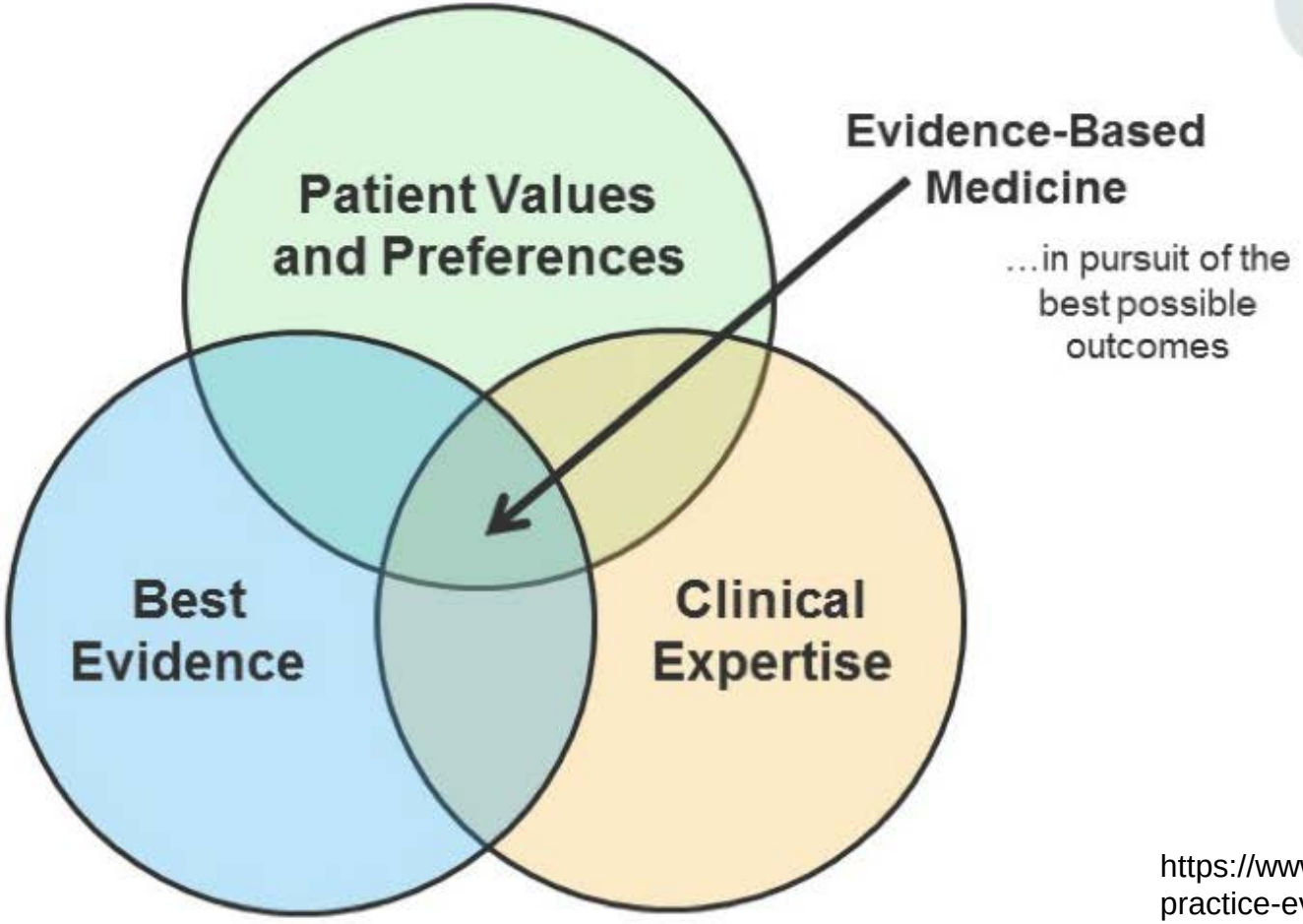
Federal regulations requires Title V and Medicaid to work cooperatively at a systems level to:

- Have a continuous liaison between the two agencies
- Jointly evaluate policies and planning that affect each organization and their joint beneficiaries
- Periodically review their joint planning structures between Title V and Medicaid.
- How access to these services and outcomes of these services is monitored.
- Written Inter-agency agreement (IAA; also called Memorandum of Understanding)

CFR § 431.615. accessed https://www.law.cornell.edu/cfr/text/42/431.615



Components of Evidence-Based Medicine



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

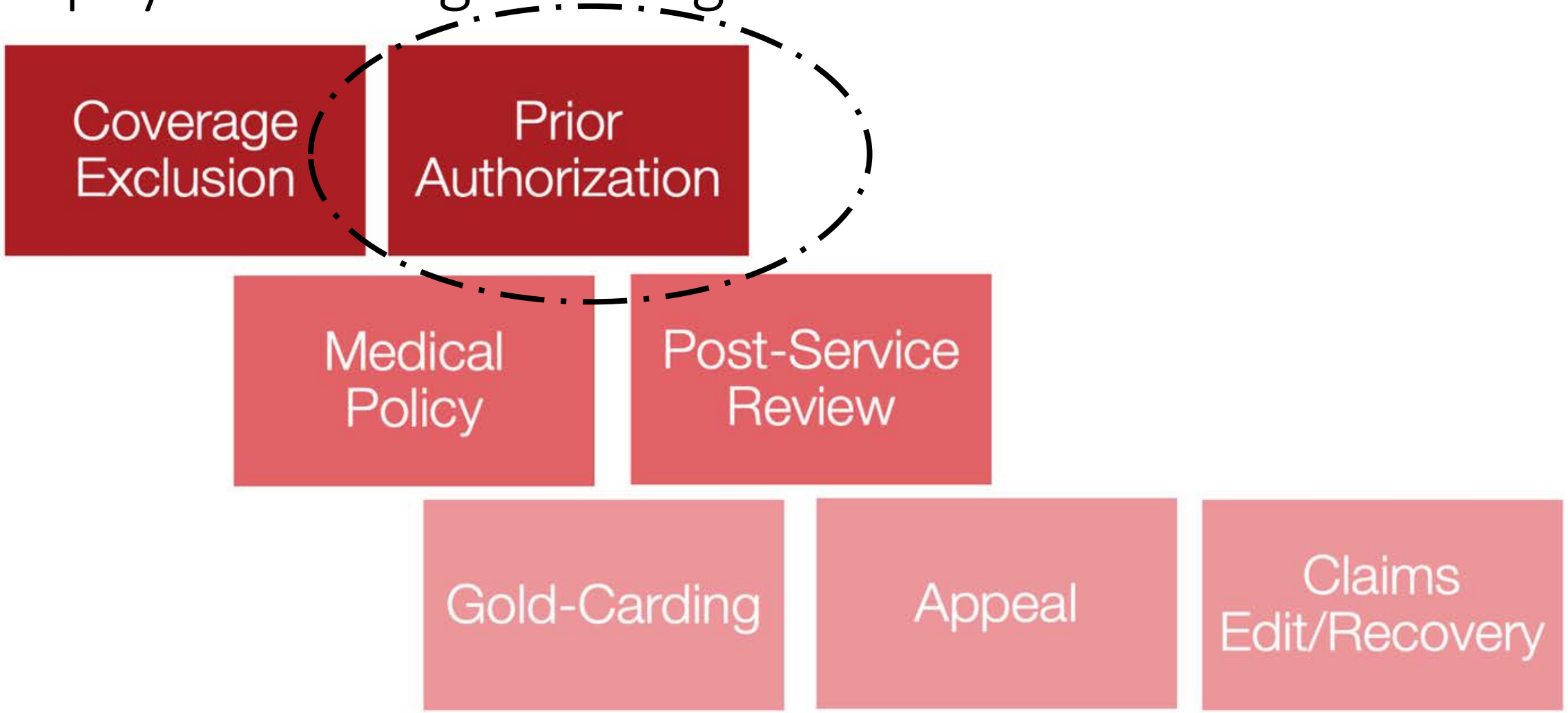
Authorization process steps

- Request
- Approval/denial
- Appeal steps
  - For Medicaid
  - For commercial/private insurance

Today

Session #3, June 2022

How payers manage testing

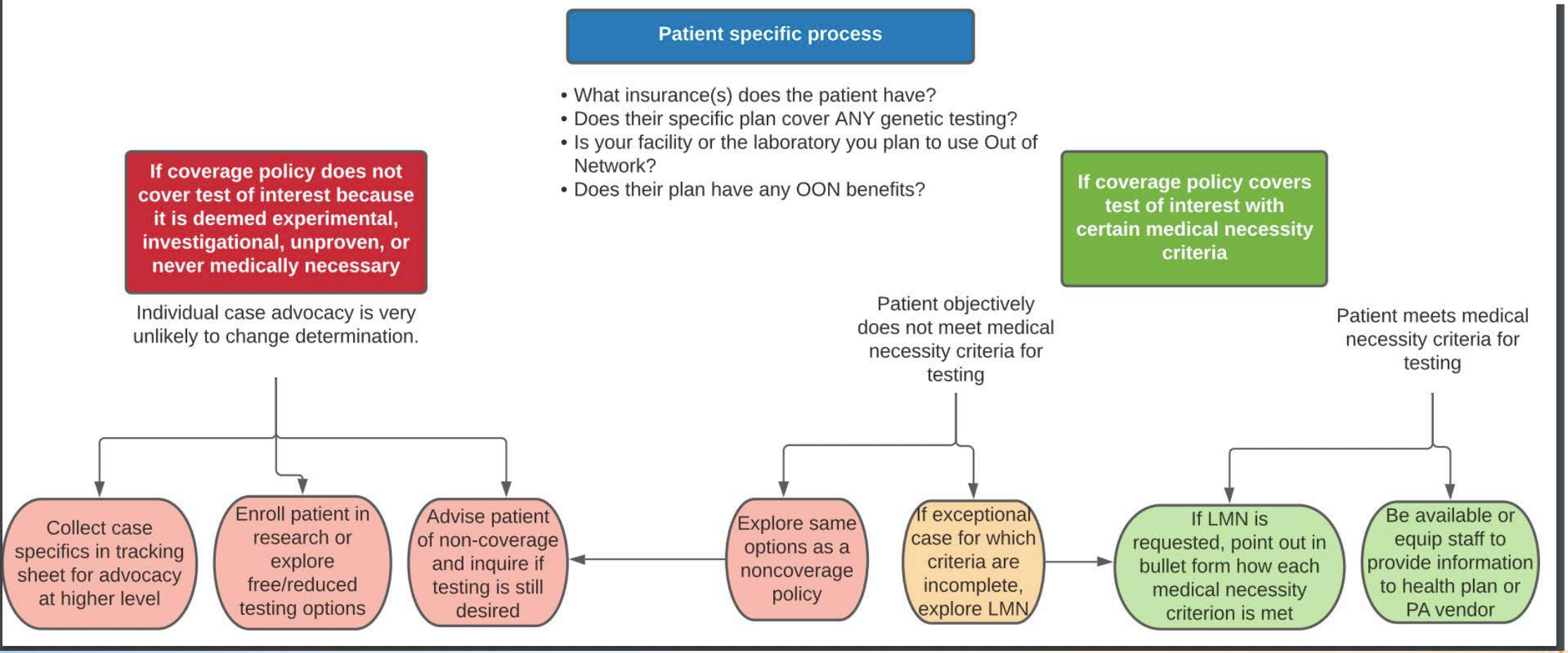


Prior Authorization request

- Standard processes
- Find or request policy – must be provided
  - But the specificity can be tricky

Prior Authorization process – Heartland RGN

https://www.heartlandcollaborative.org/educational-resources/genetic-testing-toolkit/



How to Perform a Prior Authorization

Gather the following information:

- Patient insurance and demographic information
- CPT codes for testing
  - These may be listed on the lab website for the testing being ordered
  - Or you may need to call the lab to inquire.

Helpful hint: Save CPT codes for commonly ordered tests in an easy to see location.

- ICD10 diagnostic codes for the patient
- Ordering Provider NPI #
- Laboratory NPI or TaxID # (this is only needed testing that won't be institutionally billed)
  - This information should be found on the lab website

Helpful hint: Save NPI or TaxID# for commonly used labs.

- Clinic notes and pedigree or family history

Call insurance provider line or prior authorization line

- The phone number is found on the back of the insurance card.
- State or select option for starting a prior authorization.
- **Every insurance is different**. Prior auth. may be able to be started by phone, but you may need to complete and submit a specific form or letter of medical necessity (LMN). See Insurance policy, How to write an LMN, and LMN templates sections of this toolkit.
- Ask for expected time frame on when the prior auth will be reviewed and decided upon.
- Ask how you will be notified of the decision from the prior authorization.

Helpful hint: Create a file for each payor as you go keeping the specifics of their process including any forms they require and where to fax or send the completed forms. This will save you a phone call for the next patient with this insurance.

Common questions

- What if it is denied?
  - The payor is obligated to inform you in the denial letter of routes of recourse which may include an appeal.
- What is a peer-to-peer review?
  - Some payors may have special cases or even all genetic testing cases go to a peer-to-peer review which is a conversation between the genetics provider and a "qualified" provider from the payor office.
- Does prior authorization guarantee coverage of claims?
  - For most payors, a prior authorization does not guarantee coverage of a future claim. However, many laboratories stand behind the prior authorization regarding patient payment responsibilities. This is a question you can ask the laboratory you are ordering testing from

Elements of a Letter of Medical Necessity (LMN)

Insurance information

- Provide patient name, DOB, and insurance ID and group #.

Patient health information

- Provide a clear statement about
  - the patient's clinical presentation (include ICD 10 diagnosis codes),
  - family history,
  - and differential diagnosis for underlying etiologies
    - (such as "we suspect an underlying chromosomal anomaly" or "this clinical presentation could be consistent with an underlying diagnosis of XYZ syndrome").

Test information

- Specify what test you are requesting
- Provide CPT codes for the testing you are requesting. These can be found either on the lab website or by calling the lab customer service.
- Provide laboratory name and NPI or TaxID # when possible.
- Provide cost of test when possible
- If possible provide information about validity and/or utility of testing such as ACMG or NSGC policy statements or reference to scientific publications evaluating the testing methodology in this patient set.

Why testing is important to patient care

- Clearly state how test results would affect patient care including:
  - possible changes to medical management such as screenings, medications, etc.
  - avoidance of unnecessary testing, procedures, or interventions by ruling out certain conditions.
  - how it could affect health management or health planning for rest of family.
  - how it could affect psychosocial, educational, or other social/developmental planning or interventions for the patient.
  - If applicable, detail any potential harms that could occur if testing is not pursued.

Your contact information

- Provide your contact information and offer to answer any further questions.

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)

Gather your information

Patient insurance and demographics

CPT codes for testing requested: WES 81415 (this can be lab specific)

ICD10 diagnostic codes for the patient: F84.0, F88, R56.9, D80.9, Z81.0

Ordering Provider NPI #

Laboratory NPI or TaxID # (this is only needed testing that won't be institutionally billed)

- This information should be found on the lab website

Clinic notes and pedigree or family history

- Pro-tip: write your clinic notes to meet most stringent payor test coverage policy to help meet information needed for LMNs and avoid appeals, etc.

To Whom It May Concern:

I am writing this letter to request full coverage for whole [exome/genome] sequencing to be performed by _____ (lab) for my patient, [patient name]. I recommend this testing to pursue molecular diagnosis of an underlying genetic etiology for [patient name]'s clinical presentation. It is my professional determination that testing is medically necessary and will directly impact this patient's care.

Testing is being requested due to this patient's [personal/family] history of [relevant clinical history, previous testing, etc].

The American College of Medical Genetics (ACMG) strongly recommend in their July 2021 Practice Guidelines for Exome and Genome Sequencing that exome/genome sequencing be considered as a first-line test in patients with congenital anomalies, developmental delay and/or intellectual disability. This evidence-based practice guideline also states: "Exome/genome sequencing demonstrates clinical utility for the patients and their families with limited evidence for negative outcomes and the ever-increasing emerging evidence of therapeutic benefit."[1]

Furthermore, when compared with traditional genetic testing (CMA, panels, single gene), exome/genome sequencing has a higher diagnostic yield and is more cost effective, especially when ordered early in the diagnostic evaluation. An analysis included in the recent ACMG Practice Guidelines notes a diagnostic yield of [43% for genome sequencing, 34% for exome sequencing], compared to a diagnostic yield of 21% for traditional genetic testing.[1, 2]

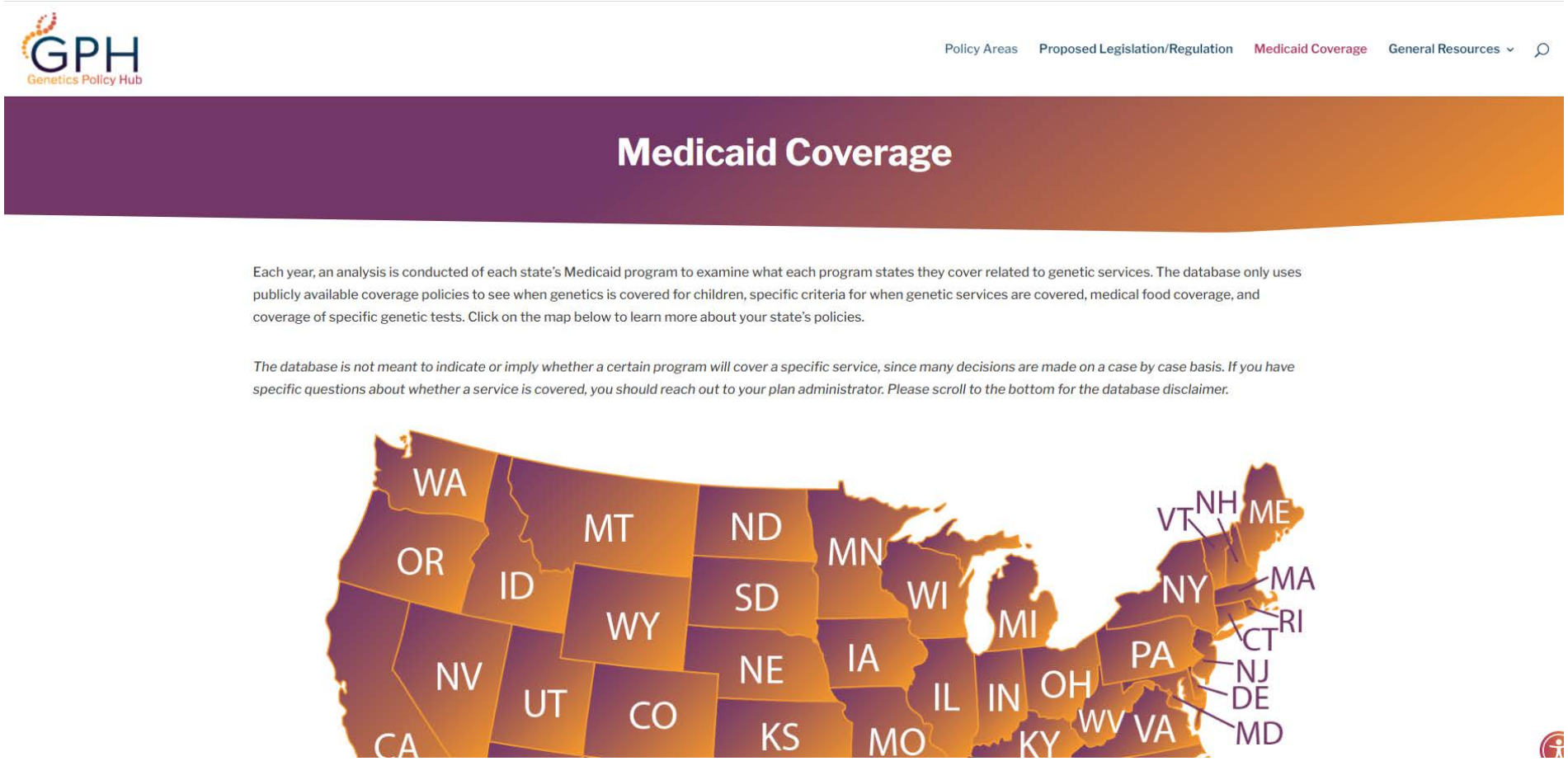
Whole [exome/genome] sequencing offered by _____(lab) will allow me to provide my patient with the best medical care by guiding appropriate medical management and treatment. Without this testing, the establishment of a clinical diagnosis will be delayed, further testing via expensive and/or invasive diagnostic procedures may be necessary, and this patient's diagnostic odyssey will continue.

The procedure code for the requested testing is [CPT code]. The diagnosis code(s) for this patient is/are [ICD-10 code(s)].

CPT codes:

WGS proband-only: 81425	WGS trio: 81425, 81426 x2
WES proband-only: 81415	WES trio: 81415, 81416 x2

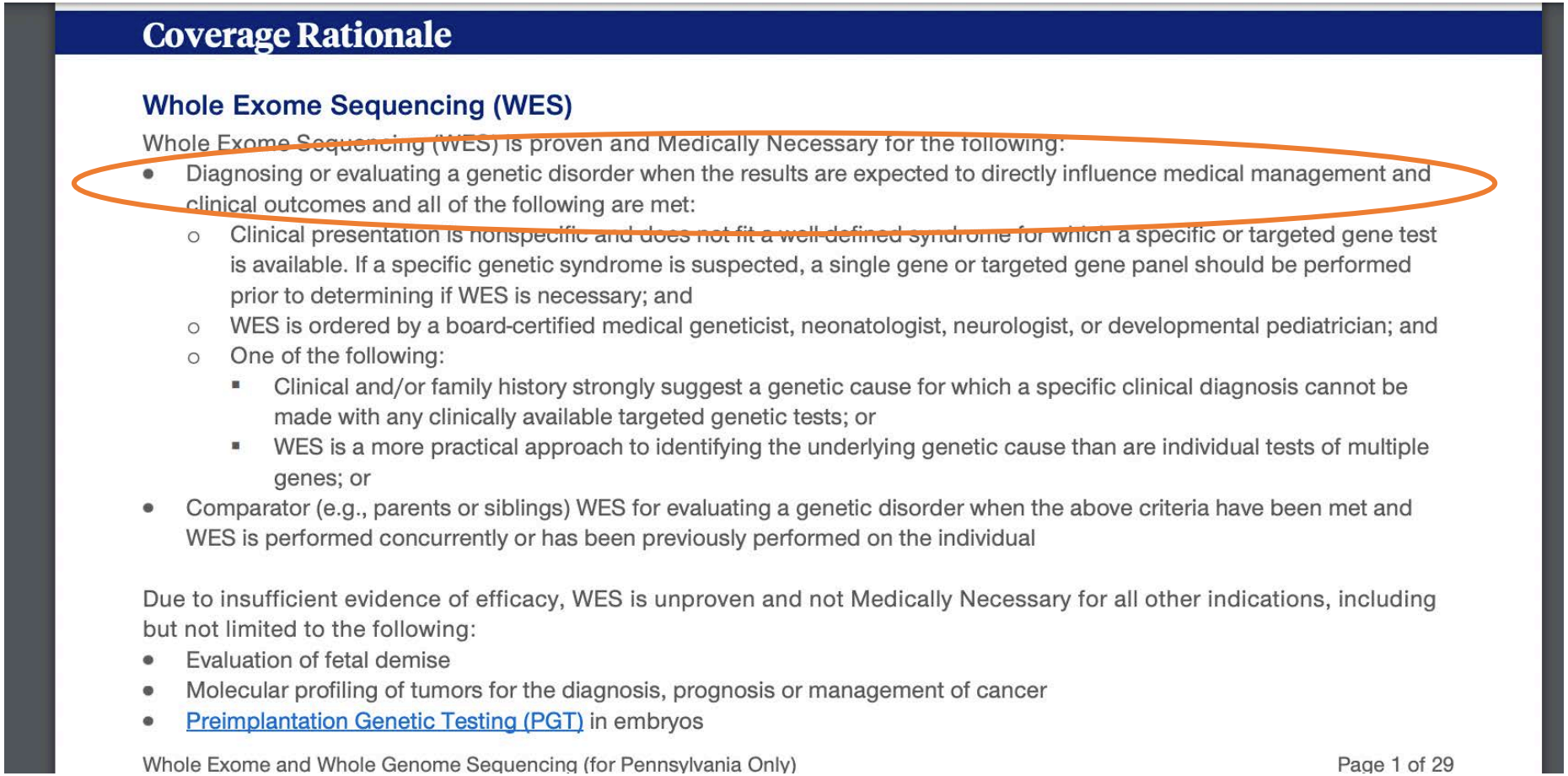
Genetics policies in state Medicaid programs



geneticspolicy.nccrcg.org

Clinical Management vs. Clinical Outcomes

One Medicaid plan



Coverage Rationale

Whole Exome Sequencing (WES)

Whole Exome Sequencing (WES) is proven and Medically Necessary for the following:

- Diagnosing or evaluating a genetic disorder when the results are expected to directly influence medical management and clinical outcomes and all of the following are met:
  - Clinical presentation is nonspecific and does not fit a well-defined syndrome for which a specific or targeted gene test is available. If a specific genetic syndrome is suspected, a single gene or targeted gene panel should be performed prior to determining if WES is necessary; and
  - WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental pediatrician; and
  - One of the following:
    - Clinical and/or family history strongly suggest a genetic cause for which a specific clinical diagnosis cannot be made with any clinically available targeted genetic tests; or
    - WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes; or
- Comparator (e.g., parents or siblings) WES for evaluating a genetic disorder when the above criteria have been met and WES is performed concurrently or has been previously performed on the individual

Due to insufficient evidence of efficacy, WES is unproven and not Medically Necessary for all other indications, including but not limited to the following:

- Evaluation of fetal demise
- Molecular profiling of tumors for the diagnosis, prognosis or management of cancer
- Preimplantation Genetic Testing (PGT) in embryos

Whole Exome and Whole Genome Sequencing (for Pennsylvania Only) Page 1 of 29

WGS – Medicaid Managed Care Policy

One plan:

A 2021 Hayes clinical utility evaluation indicates that evidence is insufficient to support the use of WGS to inform clinical action/improve outcomes in children 18 years or younger with neurological phenotypes who are lacking a diagnosis after standard diagnostic tests.

WES/ WGS ACMG Guideline

Recommendation: We strongly recommend ES and GS as a first-tier or second-tier test (guided by clinical judgment and often clinician–patient/ family shared decision making after CMA or focused testing) for patients with one or more CAs prior to one year of age or for patients with DD/ID with onset prior to 18 years of age.

And

With the anticipated further declines in cost, early use of genome-wide sequencing should continue to enable more timely diagnosis for patients with unexplained DD or multiple CAs.

https://www.acmg.net/PDFLibrary/Exome_and_genome_sequencing_pediatric_patients.pdf

Criteria are available (for WGS) but the conclusions vary:

From MCO coverage document: The researchers indicated that twice as many infants in the early group vs the delayed group received a change in management (COM) (34 of 161 vs. 17 of 165) and molecular diagnosis (55 of 176 vs 27 of 178) at 60 days. COM and diagnostic efficacy doubled in the delayed group at 90 days (to 45 of 161 and 56/178, respectively) . The study showed no measurable difference in length of stay or survival. The authors concluded that comprehensive genomic testing of acute care infants can impact clinical management and that WGS specifically positively impacts patient care and should be considered for critically ill infants with suspected genetic disease as a primary tool. Of note, this study was industry sponsored and conflicts of interest were present which could have impacted choice of methods (in particular, outcomes), or the validity of the interpretation of the findings. In addition, the findings may not be generalizable to ICUs outside of tertiary referral centers, which may have a lower incidence of genetic disease. The relevance of study findings on clinical outcomes is unclear and was not examined in this study.

From paper's abstract: In this randomized clinical trial, for acutely ill infants in an intensive care unit, introduction of WGS was associated with a significant increase in focused clinical management compared with usual care. Access to first-line WGS may reduce health care disparities by enabling diagnostic equity.

Krantz 2021; *JAMA Pediatr.* 2021;175(12):1218-1226. doi:10.1001/jamapediatrics.2021.3496

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	Treatment	Control, correct or reduce health problems found

Building a bridge
Finding out who is reviewing the letters

- Relationship with health plan medical necessity reviewers
- Meeting
  - Document decisions and assignments from meetings
  - Document expertise
  - Request fast track for genetics provider
  - Offer/ plan to share data back with MCO(s)
  - If Medicaid, share documentation with state

Buckhorn Pictographs

San Rafael Swell, Utah

Therapeutic Case

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

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

Therapeutic Case – Medical Food (Formula)
Insurance Benefit Inquiry

Information Needed

- Physician's name, NPI, office address, phone and fax numbers
- Insurance company phone number for providers to call
- Member/patient name and birthdate
- Member/patient ID number
- Diagnosis/ICD-10 code
- HCPCS code (s) and Medical Food Name

Benefit Inquiry

- Effective date of coverage
- Co-insurance percentage (in/out of network)
- Deductible amount
- If coverage is subject to the deductible
- HCPCS codes covered/excluded
- If prior authorization is required
- If service is covered under medical and/or pharmacy benefit
- Exclusion for route of administration/age/time limit
- Document the call reference number and name of the insurance representative

Medical Food (Formula)
Prior Authorization Process

Process

- Contact Insurance Company
- Physician's name, NPI, office address, phone and fax numbers
- Provide patient and insurance information
- Provide diagnosis/ICD-10 code
- Provide HCPCS code and Medical Food name
- Provide name & NPI of service provider
- Document prior authorization or reference number
- Document name of insurance representative

Medical Food (Formula)
Prior Authorization Process (cont.)

Important Documents and Information

- Medical Food order (route of administration, ICD-10 & HCPCS code)
- Physician's Letter of Medical Necessity
- Physician note (diagnosis and history, Phe levels, genetic mutation, medical food & route of administration, compliance history, adverse affect without medical food, assessment and plan, medications)
- Dietitian note (diagnosis, dietary reference intake, fluid requirement, current medications, percentage of sole source nutrition, compliance history, nutrition assessment and counseling, intervention and plan)
- DME Company contact information/NPI

*Electronic medical record templates may be revised to capture the essential information concerning diet and medical food.

Family and Provider Perspectives

Families

- How have you participated in the request for prior authorization (PA)?
  - With a provider? With clinical staff? With the managed care / insurer?
- What was good about an experience you had?
- What advice would you have for other families starting this process?
- What advice do you have for providers?

Providers

- How do you work with families to help them understand this process?

The Final Act

- The next steps for prior authorizations
  - Dealing with denials and appeals
  - System level improvements
    - Provider based authorizations (e.g., Gold carding)
    - Relationships with payers