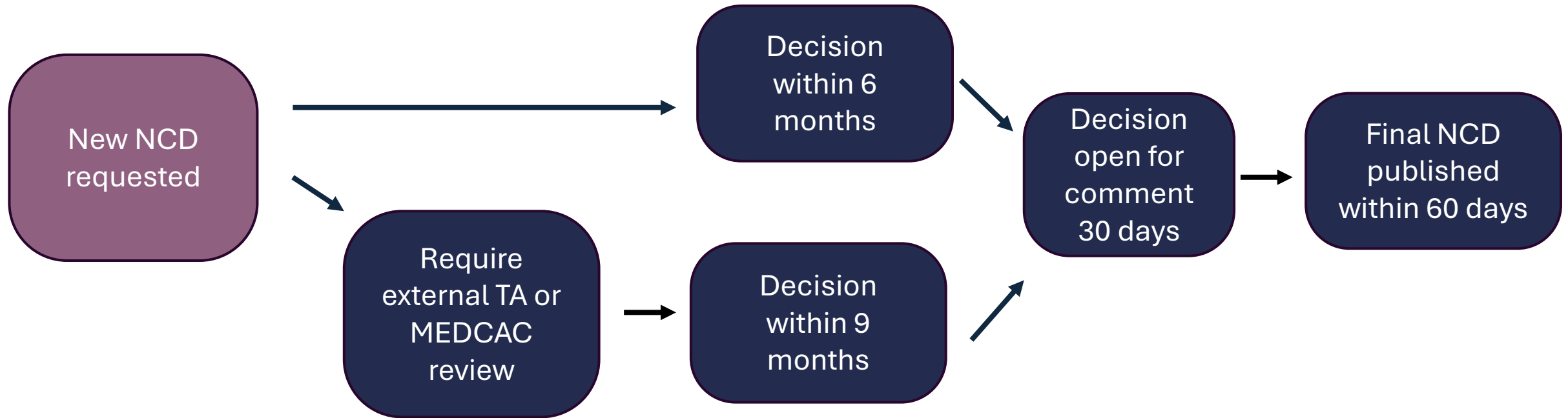




Medicare Coverage of Precision Oncology Diagnostics

National Coverage Determination (NCD) Process

Only approximately 10% of Medicare coverage policies are set via an NCD.



National Coverage Determination Dashboard



As of March 2026

National Coverage Determination Process

NCD WAIT LIST

Accepted NCD requests on the Wait List are complete based on the [NCD Request Process](#). Given the volume of requests and our current level of resources, there are times when CMS must tell requestors that an NCD request is accepted, but we cannot immediately begin the NCD process.

Diaphragm Pacemakers for Neuromuscular Disease (request for non-coverage)

Hepatitis C Screening

Hyperbaric Oxygen (HBO) Therapy for Radiation Proctitis and Radiation Enteritis

Infusion Pumps - Continuous subcutaneous insulin infusion (CSII)

Intensive Behavioral Therapy (IBT) for Obesity

Intensive Cardiac Rehabilitation (ICR) Programs

Intestinal and Multi-Visceral Transplantation for Portomesenteric Thrombosis (PMT)

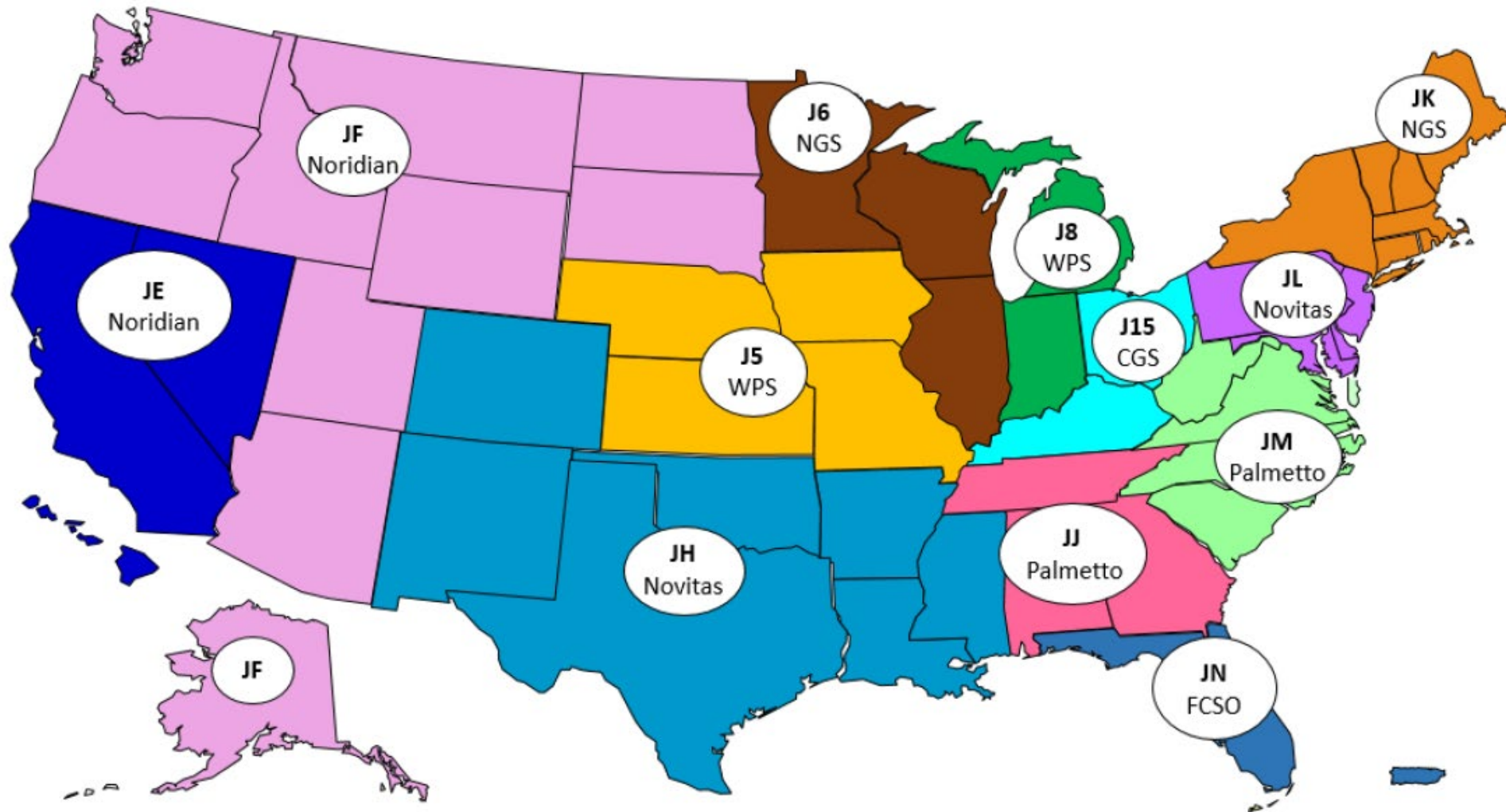
Latent Tuberculosis Infection (LTBI) Screening

Power Standing Systems

Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

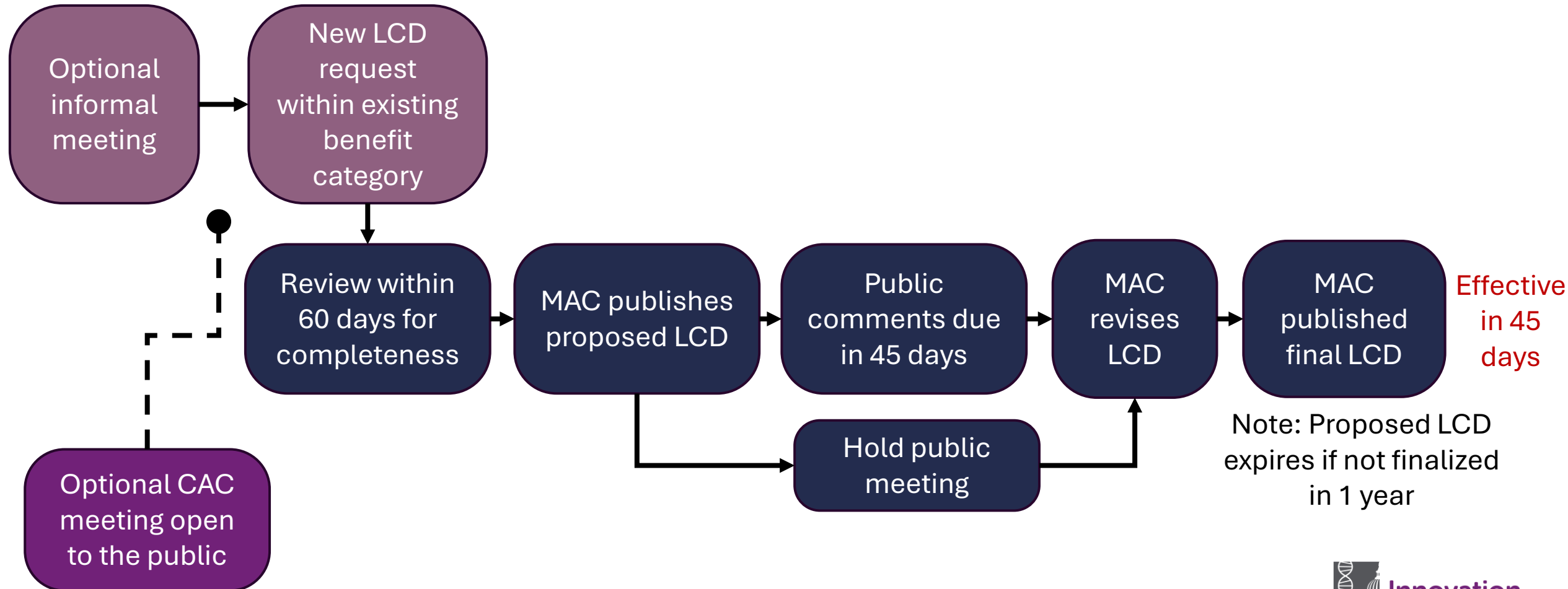
Stem Cell Transplantation - Autologous Stem Cell Transplantation (AuSCT)

Medicare Administrative Contractors (MACs)



Local Coverage Determination (LCD) Process

MACs set LCDs more readily than CMS sets NCDs



NCD 90.2: Next Generation Sequencing (NGS)

Effective date: 1/27/2020

Somatic (Acquired) Cancer

- Patient has:
 - Recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and
 - Not previously tested with same test
 - Decided to seek further treatment
- Test must have:
 - FDA authorization as a companion diagnostic
 - An FDA-approved or cleared indication for use in that cancer
 - Results provided to treating physician for management of patient

Germline (Inherited) Cancer

- Patient has:
 - Ovarian or breast cancer; and
 - A clinical indication or germline testing for hereditary breast or ovarian cancer
 - Not previously tested
- Test must have:
 - FDA approval or clearance
 - Results provided to the treating physician for management of the patient

NCD 90.2: Next Generation Sequencing (NGS) MAC Discretion

Somatic (Acquired) Cancer

- Patient has:
 - Recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and
 - Not previously tested with same test
 - Decided to seek further treatment
- Test must have:
 - Performed in a CLIA-certified laboratory
 - Ordered by a treating physician

Germline (Inherited) Cancer

- Patient has:
 - Any cancer diagnosis; and
 - A clinical indication or germline testing for hereditary cancers; and
 - A risk factor for germline cancer; and
 - Not previously tested
- Test must have:
 - Performed in a CLIA-certified laboratory
 - Ordered by a treating physician for management of a patient

Coverage Gap Example



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
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ORIGINAL ARTICLE



First-Line Camizestrant for Emerging ESR1-Mutated Advanced Breast Cancer

Authors: François-Clément Bidard, M.D., Ph.D. , Erica L. Mayer, M.D., M.P.H. , Yeon Hee Park, M.D., Ph.D., Wolfgang Janni, M.D., Ph.D., Cynthia Ma, M.D., Ph.D., Massimo Cristofanilli, M.D. , Giampaolo Bianchini, M.D.,  +18, for the SERENA-6 Study Group* [Author Info & Affiliations](#)

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- Trial used ctDNA testing for early treatment switching, i.e. monitoring.
- Showed improved progression free survival and patient reported outcomes for patients that switched treatment based on ctDNA detection of an ESR1 mutation.

Why form the CancerDx Access Alliance?



Organizations interested in engaging on the NCD 90.2: Next Generation Sequencing



No clear “home” for those who are not members of industry coalitions prioritizing the issue



Opportunity for any organization to have a “seat at the table”



Path to advocate for increased access to precision diagnostics in oncology

Confirmed Organizations as of 5/19

- American Cancer Society Cancer Action Network
- Association for Molecular Pathology
- Cancer Nation
- FORCE: Facing Hereditary Cancer Empowered
- Guardant Health
- Hope for Stomach Cancer
- Illumina
- Johnson & Johnson
- LUNGevity Foundation
- Thermo Fisher Scientific

Alliance Scope of Work



Lead and coordinate advocacy efforts in support of a reconsideration request for NCD 90.2



Provide a forum to share information, strategize, develop, and coordinate advocacy



Bring together diverse stakeholders to build consensus and develop a clear, unified message.



Ensure meaningful engagement with CMS's Coverage and Analysis Group (CAG)



If needed, leverage Congress and other policymakers.



Questions or to join the Alliance:
Jennifer@iPolicySolutions.com