Updates from Medicare

Shari Ling, MD

Deputy Chief Medical Officer

Centers for Medicare and Medicaid Services

Alliance to Advance Comprehensive Integrative Pain Management

#AACIPM

Equity in Access to Comprehensive Integrative Pain Management for People with Chronic Pain

Medicare Updates

Shari Ling, MD

Deputy Chief Medical Officer

Centers for Medicare & Medicaid Services

Alliance to Advance Comprehensive Integrative Pain Management Virtual Symposium, September 24, 2020

Disclaimer & Financial Disclosure

This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.

This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

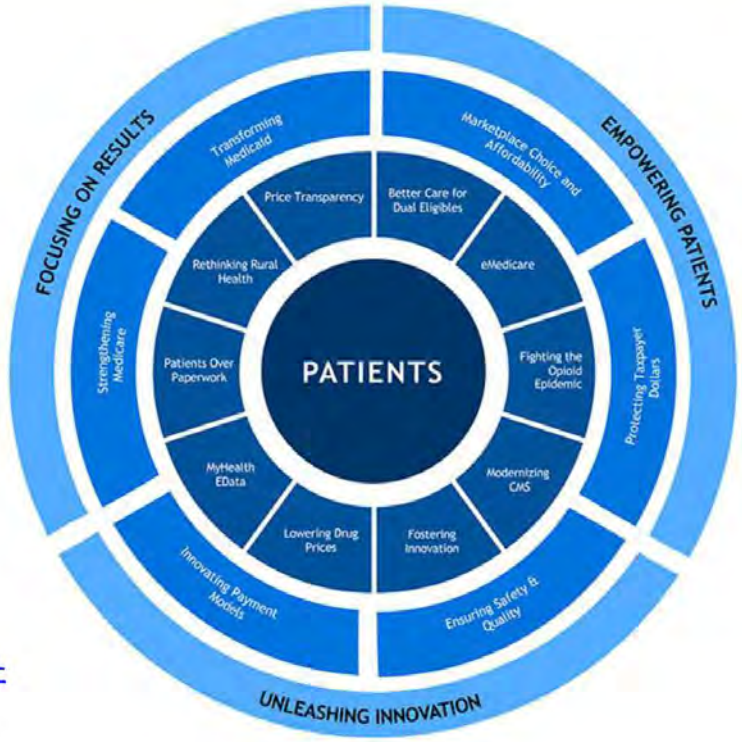
The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

No financial conflicts to disclose

Size and Scope of CMS Responsibilities

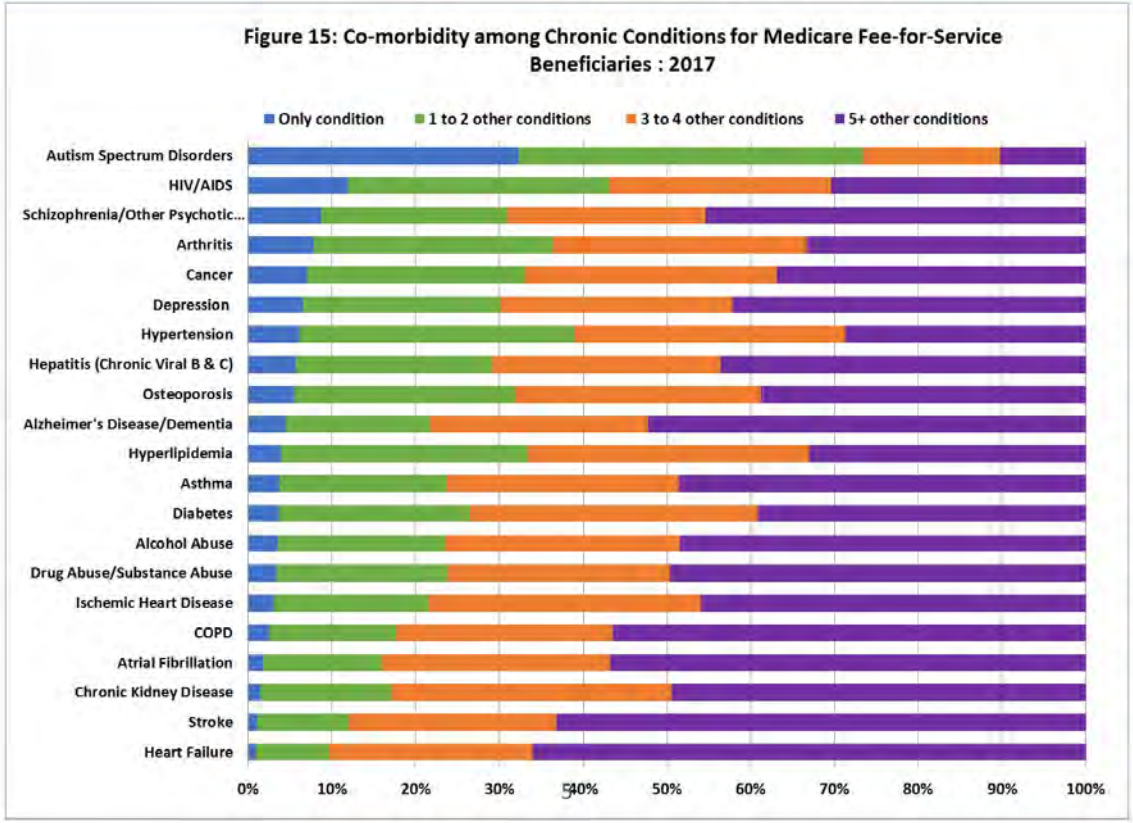
- CMS is the largest purchaser of health care in the world
- CMS covers 140 million people through Medicare, Medicaid, the Children's Health Insurance Program - roughly 1 in every 3 Americans
- Medicare spending was $750B in 2018 and is expected to experience the fastest spending growth across public and private spending (7.6 percent per year over 2019-28), largely as a result of having high projected enrollment driven by demographics
- The Medicare program alone pays out over $1.5 billion in benefit payments per day
- Through various contractors, CMS processes over 1.2 billion fee-for-service claims and answers about 75 million inquiries annually

CMS's Sixteen Strategic Initiatives
Delivering Value and Results through Competition and Innovation



Information at: https://www.cms.gov/About-CMS/Story-Page/our-16-strategic-initiatives

Co-morbidity Among Chronic Conditions in Medicare



Medicare Coverage Construct: Social Security Act 1862(a)(1)

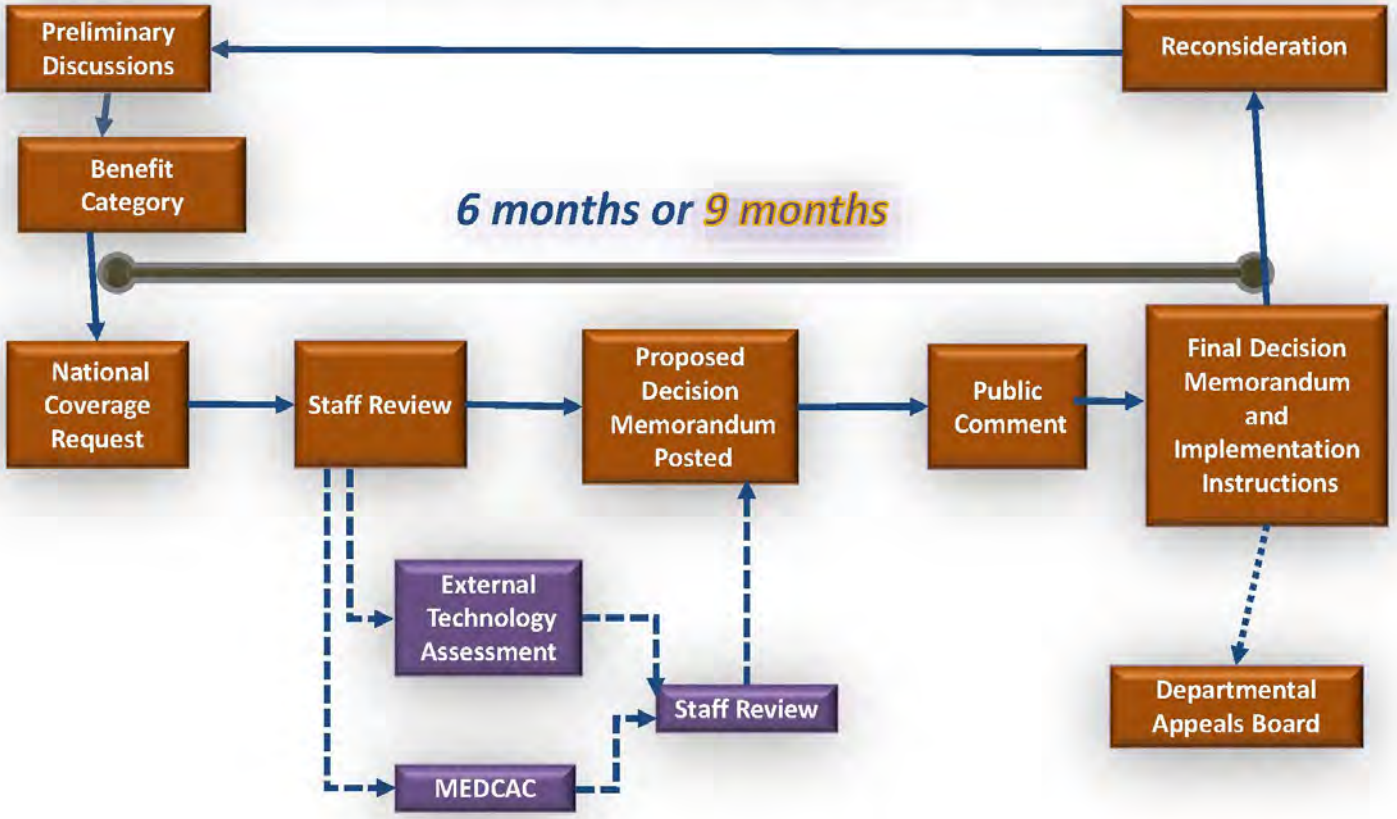
- **Reasonable and Necessary**

  Notwithstanding any other provision of this title, **no payment may be made** under part A or part B for any expenses incurred for items or services -

  - (A) which, … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, …
  - (E) in the case of research conducted pursuant to §1142, which is not reasonable and necessary to carry out the purposes of that section, …

- **Defined Benefit Program**
  - Beneficiaries
    - Age ≥ 65 years
    - Disabled individuals
    - End stage renal disease
  - Providers
  - Settings

MEDICARE NATIONAL COVERAGE PROCESS



National and Local Coverage Determinations

The evidence:

- **Sufficient** evidence to conclude that the item or service **improves clinically meaningful health outcomes** for the **Medicare population**
- Based on a comprehensive review of published evidence

National

Definition: Determination by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(a)(1)(A).

CED: § 1862(a)(1)(E) in the case of research conducted pursuant to § 1142, which is not reasonable and necessary. .

Prevention/Screening: Reasonable and necessary for the prevention or early detection of illness or disability under § 1861(d).

Local

Definition: Determination by a Medicare Administrative Contractor (MAC) with respect to whether or not a particular item or service is covered in the MAC jurisdictions under §1862(a)(1)(A).

EVIDENCE GAPS REMAIN - OLDER ADULTS ARE NEEDED IN CLINICAL TRIALS

Medicare Coverage of Acupuncture for Chronic Low Back Pain

- Effective January 1, 2020, CMS covers acupuncture for chronic low back pain
- Up to 12 visits in 90 days are covered for certain Medicare beneficiaries
- Chronic low back pain (cLBP) is defined as:
  - Lasting 12 weeks or longer
  - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease)
  - not associated with surgery
  - not associated with pregnancy
- An additional eight sessions will be covered Medicare patients demonstrating improvement
- No more than 20 acupuncture treatments may be administered annually
- Treatment must be discontinued if the patient is not improving, or is regressing

Medicare Coverage of Acupuncture for Chronic Low Back Pain

- Physicians (as defined in 1861(r)(1))* may furnish acupuncture in accordance with applicable state requirements.
- Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:
  - A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM) and
  - current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia
- Auxiliary personnel furnishing acupuncture must be under the **appropriate level** of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by CMS regulations at 42 CFR §§ 410.26 and 410.27
- All types of acupuncture, including dry needling, for any condition other than chronic low back pain are not covered by Medicare

*(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7))

Information at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295

Focus on Aspects of Acupuncture for cLBP

- Currently, acupuncturists are not recognized by CMS as Medicare providers and are not eligible to bill for acupuncture services
- Acupuncturists may furnish acupuncture as auxiliary personnel "incident to" a physician's service in certain settings, which requires supervision by a physician or other practitioner
- There is variability in education requirements across the country and the education and certification requirements specified in CMS's final decision memo help ensure qualified practitioners are furnishing acupuncture
- Requirements for chiropractic acupuncturists also vary widely from state to state
- Medicare covers manual manipulation of the spine if medically necessary to correct a subluxation when provided by a chiropractor or other qualified provider, and does not cover other services or tests ordered by a chiropractor, including acupuncture
- If a chiropractor fulfills the requirements in CMS's cLBP decision memo as auxiliary personnel, the provider would be eligible to furnish acupuncture "incident to" a physician's service
- There are several variations to traditional acupuncture including shallow needling, intradermal needling or intramuscular needling with or without a sensation of numbness, tingling, electrical sensation, fullness, distension, soreness, warmth or itching felt by a patient around an acupuncture point and CMS considers dry needling as a type of acupuncture

Additional National Policies for Medicare Beneficiaries with Chronic Pain

- Beneficiaries with multiple (two or more) chronic conditions that are expected to last at least 12 months or until death, and that place the patient at significant risk of death, acute exacerbation, decompensation, or functional decline can get **Chronic Care Management (CCM) services**, or Complex CCM services. An MLN Matters article is available at: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf.
- Medicare also covers Behavioral Health Integration Services for treatment of behavioral health, or psychiatric conditions, including substance use disorders. These services use a care team approach to facilitate and coordinate behavioral health treatment regardless of if the diagnosis or diagnoses are pre-existing or newly diagnosed. These services may benefit some beneficiaries who have a co-occurring behavioral health condition(s). Please see https://www.cms.hgov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf for more information
- These and other care management services can some beneficiaries medical care and coordination services they need to help manage their pain, and other chronic conditions and can be billed for 30-day or one month periods and may include activities performed by clinical staff. More information is at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html
- Medicare's Initial Preventive Physical Exam (IPPE), or "Welcome to Medicare" Visit, and subsequent Annual Wellness Visits (AWV) can also help detect illnesses in the earliest stages to evaluate beneficiaries' pain severity, and to review the current treatment plan

Medicare Advantage Organizations

- Medicare Advantage plans can choose to provide supplemental benefits tailored to enrollees' specific needs that are not covered under Medicare Parts A or B if they diagnose, compensate for physical impairments, diminish the impact of injuries or health conditions (e.g. pain, stiffness, loss or range of motion0, and/or reduce avoidable emergency room utilization
- Benefits could include medically approved non-opioid pain management and complementary treatment to facilitate recovery and to navigate healthcare resources, chiropractic services, acupuncture, and therapeutic massage furnished by a state-licensed massage therapist
- Massage must be ordered by a physician or medical professional to be considered primarily health-related and not primarily for the comfort or relaxation of the patient

CMS, Pain, and the SUPPORT for Patients and Communities Act

- 2018's SUPPORT Substance Use Disorder Prevention that Promotes Opioid Recovery & Treatment for Patients & Communities Act (the SUPPORT Act) outlines national strategies to help address America's opioid epidemic, and advances policies to improve the treatment of pain, and substance use disorders
- Section 6032 of the SUPPORT Act requires an Action Plan to address payment and coverage for therapies and devices that manage acute and chronic pain, recommend demonstration models, examine access to care in underserved communities, and submit a Report to Congress that summarizes the plan and describes next steps
- CMS consulted with the HHS Pain Best Practices Task Force and took public comment throughout the process of developing a Report to Congress that will be made public

The Dr. Todd Graham Pain Management Study

- Section 6086 of the Act is the Dr. Todd Graham Pain Management Study, which will provide HHS and CMS with key information about services delivered to Medicare beneficiaries with acute or chronic pain, help in understanding the current landscape of pain relief options for Medicare beneficiaries, and inform decisions around payment and coverage for pain management interventions, including those that minimize the risk of substance use disorders
- CMS is working with our HHS partners at the Agency for Healthcare Research and Quality and the Office of the Assistant Secretary for Planning and Evaluation to prepare a Report to Congress that will be public
- CMS held a Medicare Learning Network listening session on August 27 to get information from Medicare providers and suppliers about barriers to care, gaps in coverage, care for beneficiaries who have pain and a substance use disorder, and pain care during the COVID-19 pandemic

The Dr. Todd Graham Pain Management Study (continued)

- A similar session was held with pain advocacy groups and persons with pain on September 16

Stakeholder comments included:

- Cost and reimbursement are barriers for patients, and providers
- Access to pain care can be problematic
- Telehealth flexibilities accelerated by the pandemic have helped patients and providers
- More and better evidence is needed for non-opioid pain therapies
- Some people with pain already felt isolated before the pandemic

- CMS also met with our Advisory Panel on Outreach and Education yesterday to gather information: https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE

Section 2003

- Electronic prescribing of controlled substances (EPCS) is the e-prescribing of drugs classified as controlled substances (includes opioid medications)
- EPCS is allowed in all 50 states and the District of Columbia and more than half the states have laws requiring it
- The SUPPORT Act requires that all controlled substances of Part D drugs be prescribed electronically
- Almost all pharmacies support EPCS prescriptions
- CMS has issued a Request for Information (RFI) on section 2003 to seek broad stakeholder feedback on implementing the prescription drug program, including on circumstances and processes to waive the secure transmission requirement, with several specific cases for consideration listed in statute, and enforcement and penalty requirements for future rulemaking
- The RFI is open until October 5 for comment, pain stakeholders may want to register their reaction to statutory requirements: https://www.federalregister.gov/documents/2020/08/04/2020-16897/medicare-program-electronic-prescribing-of-controlled-substances-request-for-information-rfi

Section 2002

- Section 2002 of the SUPPORT Act requires that Medicare's "Welcome" visit and the Annual Wellness Visit include a new screening for potential substance use disorders, a review of any current opioid prescriptions, an evaluation of the person's severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and referral to a specialist, as appropriate
- This proposal is included in the Notice of Proposed Rulemaking for the 2021 Medicare Physician Fee Schedule, which is open for public comment until October 5; pain stakeholders may want to weigh in
- The proposed rule can be downloaded from the Federal Register at: https://www.federalregister.gov/public-inspection

Thank you!