CMS Perspectives on Payment, Quality, and Value in Pain Medicine

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I am an anesthesiologist and still clinically active

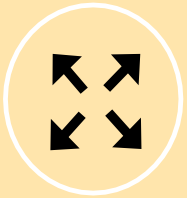
CMS Strategic Pillars

ADVANCE EQUITY

Advance health equity by addressing the health disparities that underlie our health system

EXPAND ACCESS

Build on the Affordable Care Act and expand access to quality, affordable health coverage and care



ENGAGE PARTNERS

Engage our partners and the communities we serve throughout the policymaking and implementation process

DRIVE INNOVATION

Drive Innovation to tackle our health system challenges and promote value-based, person-centered care

PROTECT PROGRAMS

Protect our programs' sustainability for future generations by serving as a responsible steward of public funds

FOSTER EXCELLENCE

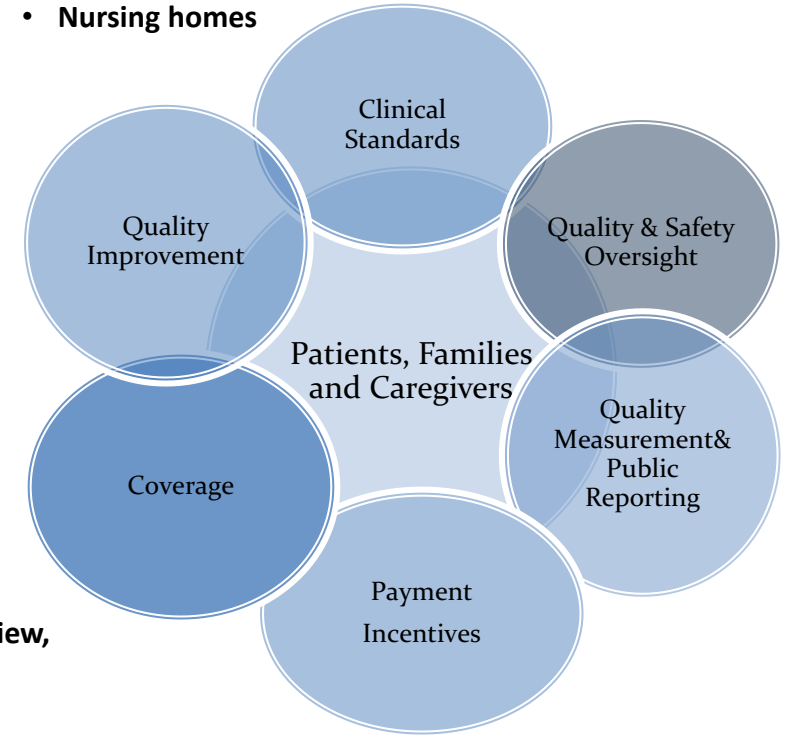
Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations

CMS/CCSQ Authorities & Programs

- Hospital Inpatient Quality
- Hospital Outpatient
- In-patient psychiatric hospitals
- Cancer hospitals
- Nursing homes

- Home Health Agencies
- Long-term Care Acute Hospitals
- In-patient rehabilitation facilities
- Hospices
- Other facilities

- Quality Improvement Organizations
- Hospital Innovation & Improvement Networks
- Rapid Cycle Evaluation



- CLIA Program
- Clinical Laboratories
- Target surveys
- Quality Assessment & Performance Improvement

- National & Local policies
- Mechanisms to support innovation (CED, parallel review, other)

- Hospitals, Home Health Agencies, Hospices, ESRD facilities, Nursing Home, Clinician and other Care Compare

- VBP hospitals, SNF, HHA, ESRD
- Payment adjustments HAC, hospital RRP
- Physician Quality Payment Program (QPP)

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

National and Local Coverage Determinations

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).

The evidence:

- **Sufficient** evidence to conclude that the item or service **improves clinically meaningful health outcomes** for the **Medicare populati**on
- 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

EVIDENCE GAPS REMAIN - OLDER ADULTS ARE NEEDED IN CLINICAL TRIALS

Local Coverage Determination (LCD)
Epidural Steroid Injections for Pain Management
Covered Indications

- Epidural steroid injection (ESI) will be considered medically reasonable and necessary when the following requirements are met:
  - History, physical examination, and concordant radiological image-based diagnostic testing that supports one of the following[5]:
    - Lumbar, cervical or thoracic radiculopathy, radicular pain and/or neurogenic claudication due to disc herniation, osteophyte or osteophyte complexes, severe degenerative disc disease, producing foraminal or central spinal stenosis[5] **OR**
    - Post-laminectomy syndrome,[6-8] **OR**
    - Acute herpes zoster associated pain.[6]
- **AND**
  - Radiculopathy, radicular pain and/or neurogenic claudication is severe enough to greatly impact quality of life or function. An objective pain scale or functional assessment must be performed at baseline (prior to interventions). The same scale* must be used at each follow-up for assessment of response.
- **AND**
  - Pain duration of at least four (4) weeks, and the inability to tolerate noninvasive conservative care or medical documentation of failure to respond to four (4) weeks of noninvasive conservative care **or** acute herpes zoster refractory to conservative management where a four (4) week wait is not required.[6,9]

- The ESIs must be performed under computed tomography (CT) or fluoroscopy image guidance with contrast[10]
- Transforaminal ESIs (TFESIs) involving a maximum of two (2) levels in one spinal region are considered medically reasonable and necessary.
- Caudal ESIs and interlaminar ESIs (ILESIs) involving a maximum of one level are considered medically reasonable and necessary.[11]
- It is considered medically reasonable and necessary to perform TFESIs bilaterally only when clinically indicated.
- Repeat ESI when the first injection directly and significantly provided improvement of the condition being treated may be considered medically reasonable and necessary when the medical record documents at least 50% of sustained improvement in pain relief and/or improvement in function measured from baseline using SAME scale* for at least three months.[7,8] If a patient fails to respond well to the initial ESI, a repeat ESI after 14 days can be performed using a different approach, level and/or medication, if appropriate, with the rationale and medical necessity for the second ESI documented in the medical record.
- The ESIs should be performed in conjunction with conservative treatments.[9]
- Patients should be part of an active rehabilitation program, home exercise program or functional restoration program.[10,12]

Local Coverage Determination (LCD)
Epidural Steroid Injections for Pain Management
Limitations

- It is not considered medically reasonable and necessary to perform multiple blocks (ESIs, sympathetic blocks, facet blocks, trigger point injections, etc.) during the same session as ESIs, with the exception of a facet synovial cyst and ESI performed in the same session.
- Use of Moderate or Deep Sedation, General Anesthesia, or Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for these procedures and therefore, is not considered medically reasonable and necessary.[16] Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice. In exceptional and unique cases, documentation must clearly establish the need for such sedation in the specific patient.
- ESIs to treat non-specific low back pain (LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, pain from neuropathy from other causes, or cervicogenic headaches are considered investigational and therefore are not considered medically reasonable and necessary.[6,17,18]
- ESIs are limited to a maximum of four (4) sessions per spinal region in a rolling twelve (12) month period.[7]
- It is not considered medically reasonable and necessary for more than one spinal region to be injected in the same session.[11]
- It is not considered medically reasonable and necessary to perform TFESIs at more than two (2) nerve root levels during the same session.[11]
- It is not considered medically reasonable and necessary to perform caudal ESIs or ILESIs at more than one (1) level during the same session.[11]
- It is not medically reasonable and necessary to perform caudal ESIs or ILESIs bilaterally.[14]
- It is not medically reasonable and necessary to prescribe a predetermined series of ESIs.[8]
- It generally would not be considered medically reasonable and necessary for treatment with ESI to extend beyond 12 months.[19,20] Frequent continuation of ESIs over 12 months may trigger a focused medical review. Use beyond twelve months requires the following:
  - Pain is severe enough to cause a significant degree of functional disability or vocational disability.
  - The ESI provides at least 50% sustained improvement of pain and/or 50% objective improvement in function (using same scale as baseline).
  - Rationale for the continuation of ESIs including, but not limited to, patient is high-risk surgical candidate, the patient does not desire surgery, recurrence of pain in the same location relieved with ESIs for at least three months.
  - The primary care provider must be notified regarding continuation of procedures and prolonged repeat steroid use.

National Policies for Medicare Beneficiaries with Chronic Pain

- **Additional National Policies to Care for Medicare Beneficiaries with Chronic Pain**

- Chronic Care Management (CCM) services, or Complex CCM services for people with multiple (two or more) chronic conditions that are:
  - Expected to last at least 12 months or until death, and
  - Place the patient at significant risk of death, acute exacerbation, decompensation, or functional decline
- 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 is pre-existing or newly diagnosed
  - May benefit some beneficiaries who have a co-occurring behavioral health condition(s)

National Policies for Medicare Beneficiaries with Chronic Pain (continued)

- Medical care and coordination services to help manage pain and other chronic conditions
  - Can be billed for 30-day or one month periods
  - May include activities performed by clinical staff
- Medicare's Initial Preventive Physical Exam (IPPE) or "Welcome to Medicare" Visit, and Annual Wellness Visits (AWV)
  - Help detect illnesses in the earliest stages to evaluate beneficiaries' pain severity,
  - Review the current treatment plan

Medicare Coverage of Acupuncture for Chronic Low Back Pain

- Starting in 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 annually
- Treatment must be discontinued if the patient is not improving or is regressing

Medicare Advantage Plans, Chronic Illness & Pain

- Medicare Advantage plans can choose to provide supplemental benefits tailored to enrollees' specific needs that are not covered under Original Medicare Part A and Part B to
  - Better tailor benefit offerings
  - Address gaps in care
  - Improve chronic illness outcomes
  - May include medically-approved non-opioid pain management and complementary treatment to facilitate recovery and to navigate healthcare resources, chiropractic services, complementary therapies, social needs benefits, services that support self-direction, structural home modifications, caregiver supports

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

- Supports Substance Use Disorder Prevention and Promotes Opioid Recovery & Treatment
  - Outlines national strategies to help address America's opioid epidemic
  - Advances policies to improve the treatment of pain and substance use disorders
- The SUPPORT Act (Section 6032) 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
  - Submit a Report to Congress that summarizes the plan and describes next steps
- HHS Pain Best Practices Task Force developed the Pain Management Best Practices Inter-agency Task Force Report.

The Dr. Todd Graham Pain Management Study

- Section 6086 of the SUPPORT Act is the Dr. Todd Graham Pain Management Study
- Provides HHS and CMS with key information about
  - Services delivered to people with Medicare with acute or chronic pain
  - Help in understanding the landscape of pain relief options for people with Medicare
  - Inform decisions around payment and coverage for pain management interventions, including those that minimize the risk of substance use disorders
- Highlights:
  - 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

SUPPORT Act Section 2002

- Requires Medicare's "Welcome" visit and the Annual Wellness Visit include:

  - New screening for potential substance use disorders
  - Review of any current opioid prescriptions
  - Evaluation of the person's severity of pain and current treatment plan
  - Information on non-opioid treatment options
  - referral to a specialist, as appropriate

SUPPORT Act Section 2003

- Electronic prescribing of controlled substances (EPCS) is the e-prescribing of drugs classified as controlled substances (includes opioid medications)
  - Allowed in all 50 states and the District of Columbia and more than half the states have laws requiring it
  - All controlled substances for Part D must be prescribed electronically
  - Almost all pharmacies support EPCS prescriptions
  - Affects many patients who are still impacted by the burdens of paper prescribing
- CMS issued guidance in the final 2021 Physician Fee Schedule indicating we will delay imposing penalties for noncompliance until January 2022, to minimize the burden on prescribers

Pain Management Policies in Calendar Year 2022 Rulemaking

- Payment for Non-Opioid Pain Management Drugs and Biologicals Under Section 6082 of the SUPPORT Act
  - CMS identified the ambulatory surgical center (ASC) setting as a setting in which there was a significant financial disincentive to use non-opioids instead of opioids.
  - For CY 2022, CMS modified its previous policy to provide for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the ASC setting when those products are FDA approved and have been FDA indicated for pain management or as an analgesic and have a per-day cost above the OPPS drug packaging threshold (greater than $130 for CY 2022)
  - For CY 2022, 4 non-opioid pain management drugs that function as surgical supplies met these requirements:
    - Exparel (injection bupivacaine liposome),
    - Omidria (phenylephrine and ketorolac ophthalmic irrigation solution),
    - Zynrelef (bupivacaine and meloxicam instillation)
    - Xaracoll (bupivacaine, collagen-matrix implant)
  - CMS also solicited comment on whether similar financial disincentives existed to support expanding this policy to the OPPS. We received feedback from a wide variety of stakeholders, which we will continue to consider for future rulemaking.

Innovation At The Centers For Medicare And Medicaid Services: A Vision For The Next 10 Years

Chiquita Brooks-LaSure, Elizabeth Fowler, Meena Seshamani, Daniel Tsai
Health Affairs Blog August 12, 2021

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

FEBRUARY 17, 2022

Health Care Safety during the Pandemic and Beyond — Building a System That Ensures Resilience

Lee A. Fleisher, M.D., Michelle Schreiber, M.D., Denise Cardo, M.D., and Arjun Srinivasan, M.D.

The health care sector owes it to both patients and its own workforce to respond now to the pandemic-induced falloff in safety by redesigning our current processes and developing new approaches that will permit the delivery of safe and equitable care across the health care continuum during both normal and extraordinary times. We cannot afford to wait until the pandemic ends.

udio interview
Dr. Fleisher is
e at NEJM.org

Your role!

JAMA Health Forum™

Viewpoint

Shaping Medicare's Health Care Regulations

Sheila C. Blackstock, BSN, MSM, JD; Adam C. Richards, MA; Lee A. Fleisher, MD

The CMS strives to establish requirements that promote quality and safety at a national level while allowing innovation. Rulemaking and other flexibilities can serve as a valuable lever during a public health crisis to relieve pressure within the health care system and equip health care organizations with the agility needed to promote patient safety and quality outcomes. Commenting on proposed regulations is a key opportunity for interested persons or groups to help shape the direction of Medicare and other federal health programs.

Thank you!

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