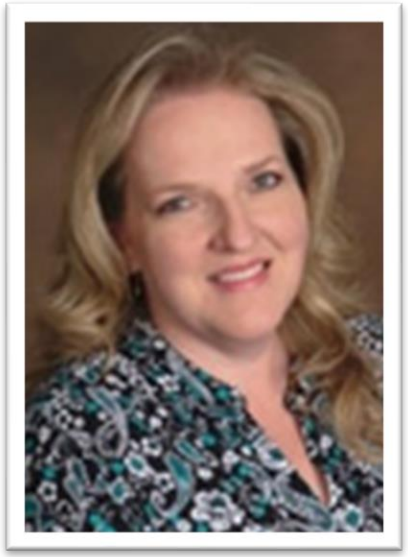
Facet Joint Interventions: Prepare for Prior Authorizations and More Medicare Audits

A WEBINAR PRESENTED ON JUNE 6, 2023

decisionhealth

Presented By



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Learning Objectives

- At the completion of this educational activity, the learner will be able to:
  - Follow Medicare's rules for prior authorization of facet joint interventions
  - Train staff to avoid the top documentation and coding errors that will put their practice's facet joint intervention claims at risk
  - Bonus: Determine whether their practice must follow the uniform LCDs for urine drug testing, SI joint injections, and procedures

Prior Authorization (PA) Program for Certain Hospital Outpatient Department (OPD) Services Operational Guide

- https://www.cms.gov/files/document/opd-operational-guide.pdf

- 2.1- OPD Services That Require Prior Authorization CMS added Facet Joint Interventions to the nationwide prior authorization process for hospital outpatient department (OPD) services.
- OPD providers can start submitting the prior authorization requests (PARs) on June 15, 2023, for dates of service on or after July 1, 2023.
- This service category will be in addition to the existing list of services requiring prior authorization, which are 6 April 11, 2023 blepharoplasty, botulinum toxin injection, rhinoplasty, panniculectomy, vein ablation, implanted neurostimulators, and cervical fusion with disc removal.

Applicable CPT Codes

- 64490 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
  - 64491 second level;
  - 64492 third and any additional level(s)

- 64493 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level;
  - 64494 second level;
  - 64495 third and any additional level(s)

- 64633 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
  - 64634 each additional facet joint

- 64635 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
  - 64636 each additional facet joint

Applicable place of service

- **19** (Off-campus outpatient hospital)
- **22** (On-campus outpatient hospital)

Prior Authorization Request (PAR)

- 3 – Prior Authorization Request (PAR)
  - The PAR must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.
  - The PAR will not be accepted after the service has been completed.
  - The PAR must include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules.

- Submission Documentation
  - Beneficiary Information
  - Hospital OPD Information
  - Physician Information
  - Requestor Information
  - Other Information
    - HCPCS, ICD-10, CPT, # Units

Sending a PAR Requesters

Options for submitting PARs to the A/B MACs:

- Mail
- Fax
- Electronic submission of medical documentation (esMD), content type 8.5*, or 4) CMS- approved electronic portal (A/B MAC specific).

* For more information about submissions through esMD, see www.cms.gov/esMD or contact your A/B MAC.

Review of the PAR

- An affirmative or non-affirmative decision will be issued to the provider.
- A provisional affirmation will be issued to the provider if it is decided that applicable Medicare coverage, coding, and payment rules are met.
- A non-affirmation will be issued to the provider if it is decided that applicable Medicare coverage, coding, and payment rules are not met.
- A unique tracking number (UTN) will be assigned to each PAR.
- If you receive a non affirmative decision, the MAC will provide detailed information about all missing and/or non-compliant information that resulted in the non-affirmative decision.

Review Decisions and Timeframes

- Time frame for decision dependent on the service selected and documentation submitted for PAR
  - Initial Submission
    - First PAR sent to the contractor
    - MAC will complete review and send initial decision within 10 business days following receipt of the initial request

Review Decisions and Timeframes

- Time frame for decision dependent on the service selected and documentation submitted for PAR
  - Resubmission
    - Subsequent resubmission to correct an error or omission identified during a PA decision
    - MAC post mark or fax notification of the decision of the resubmitted requests to the provider or beneficiary within 10 business days following receipt of the resubmission request
    - The provider should review the detailed decision letter that was provided.
    - A provider may resubmit a PAR an unlimited number of times upon receipt of a non-affirmative decision.
      - The UTN will be assigned with each PA resubmission request.

Decision Letter

- Decision letters with the UTN will be sent to the requester using the method the PAR was received
- The MAC will have the option to send a copy of the decision to the requester via fax if a valid fax number was provided, even if the submission was sent via mail.
- The requester(s) will be notified to hold their claim and not submit it until the UTN is received (in order to avoid a claims payment denial) if the MAC exercises the option to send the PA decision without the UTN.
- PAR can be sent by the physician/practitioner on behalf of the hospital OPD.
- Physicians/practitioners who submit the PAR on behalf of the OPD should include their contact information on the PAR cover sheet, in addition to the hospital OPD's contact information.
- If the physician/ practitioner is not the requester and would like to obtain a copy of the decision letter, they should contact the hospital OPD.
- Decision letters sent via electronic submission of medical documentation (esMD) are not available at this time.

Decisions

- Provisional Affirmation PA Decision
  - A provisional affirmation PA decision is a preliminary finding that a future claim submitted to Medicare for the service(s) likely meets Medicare's coverage, coding, and payment requirements.
  - Provisional affirmation PA decision is valid for 120 days from the date decision was made.

- Non-Affirmation PA Decision
  - A non-affirmation PA decision is a preliminary finding that if a future claim is submitted to Medicare for the requested service does not likely meet Medicare's coverage, coding, and payment requirements.
  - MAC will provide the PAR requester notification of what required documentation is missing or noncompliant with Medicare requirements via fax, mail, or the MAC provider portal (when available).

Exemption

- CMS may elect to exempt a hospital OPD provider from PA upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules.
- This exemption would remain in effect until CMS elects to withdraw the exemption.
- CMS or its contractors would exempt providers that submitted at least 10 requests and achieve a PA provisional affirmation threshold of at least 90 percent during an annual assessment.
- By achieving this percentage of provisional affirmations, the provider would be demonstrating an understanding of the requirements for submitting accurate claims.
- Notice of an exemption or withdraw of an exemption will be provided at least 60 days prior to the effective date.

Validation Period for Prior Authorization Decisions

Validation Period for Prior Authorization Decisions

- PAR decisions and UTNs for these services are valid for 120 days.
- The decision date shall be counted as the first day of the 120 days.
  - For example: if the PAR is affirmed on January 1, 2021, the PAR will be valid for dates of service through April 30, 2021. Otherwise, the provider will need to submit a new PAR.

Expedited Review

- A provider may request an expedited review if the following are in jeopardy:
  - Life
  - Health
  - Ability to regain maximum function

Prior Authorization for Facet Joint Interventions—Updated May 15, 2023

- Providers that perform facet joint intervention procedures in a Hospital Outpatient Department (HOPD) setting should start submitting Prior Authorization Requests (PAR) on June 15, 2023, for services scheduled on or after July 1, 2023.

- Providers should ensure that the PAR or documentation clearly indicates what facet joint intervention they are planning.
  - For example, if a provider submits a PAR for CPT 64493 for a second Medial Branch Block (MBB), they should ensure that the PAR or documentation notes that the request is for the second injection for the reviewer to determine if coverage criteria is met.

https://www.wpsgha.com/wps/portal/mac/site/medical-review/news-and-updates/pa-facet-joint-interventions/!ut/p/z1/jZFBT8MwDIV_C4ceU3urNlXcCoJVU6txGYRcULa5aacuiZKslfj1BO2EBKW-2fqe_fQMAjgILYdOydAZLfvYv4v1x0tZrstFjtVuWSMW9fNr9pRXD7vFCt4mgAw3GYg5evyjCpynnwDE9PrtfwdiAktXP9YKhJWhZZ1uDHBNo2dSn9jVnmQgD9xK1sgjBXY2nQ4RC-QG0t85-uhSTNy55TTDqerN4faUQh-yPFpy1JAjl15dHLchWH-fYILjOKbKGNVTejSXBH-TtMYH4D9JsJf9nn9WJZ5X_VAVd19BYnUL/dz/d5/L2dBISEvZ0FBIS9nQSEh/#

Facet Joint Interventions

Facet Joint Interventions

- Facet Joint Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** the following criteria:
  1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale*
  2. Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated)
  3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst)
  4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.

Facet Joint Interventions

Second Diagnostic Injection

- Patient meets criteria for first injection
- 80% relief consistent with the agent used
- Functional improvement documentation recommended
- More than two levels considered under unique circumstances

  – REMEMBER: Append modifier KX to diagnostic blocks

Facet Joint Denervation

- Initial Thermal RF
  - After two diagnostic MBB with 80% relief consistent with the agent used
- Repeat Thermal RF
  - Minimum of consistent 50% improvement in pain for at least 6 months
  - Or at least 50% consistent improvement in ability to perform previously painful movements and ADLs as compared with baseline
- *Pain assessment must be performed and documented at baseline, after each diagnostic procedure using the **same** pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

Therapeutic Facet Joint

Therapeutic Facet Joint

- IA diagnostic injection only if MBB cannot be performed
- Document why the patient is not a candidate for RF
- Two diagnostic injections with 80% relief for the duration of the agent used
- Repeat therapeutic with
  - at least 50% consistent relief for three months
  - Or at least 50% consistent improvement in ability to perform previously painful movements

TPE Denial Examples (Facets)

Review Summary Rationale

This decision was made because: medical necessity is not met. Conflicting information in procedure report narrative. Unable to determine what lumbar levels were injected.

The documentation does not support medical necessity for medial branch block injections and/or intraarticular facet joint injections. The documentation was missing:

- Procedure/operative report has conflicting information

Review Summary Rationale

This decision was made because:

The documentation does not support medical necessity for medial branch block injections and/or intraarticular facet joint injections. The documentation was missing:

- Three months of moderate to severe pain
- Failure to respond to non-invasive conservative therapy, has conflicting information, as patient intake indicates pain gradual onset, last three years, conservative treatment indicates pain for decades

TPE Denial Examples (Facets)

Review Summary Rationale

This decision was made because:

The documentation does not support medical necessity for medial branch block injections and/or intraarticular facet joint injections. The documentation was missing:

- Pre procedural pain assessment

Decision
After medical review the services will be denied.

The documentation does not support the required elements for the service billed. The documentation is missing:

- Post procedural pain assessment on the date of service

TPE Denial Examples (Facets)

Review Summary Rationale

This decision was made because:

The documentation does not support medical necessity for diagnostic medial branch block injections and/or intraarticular facet joint injections. The documentation was missing:

- Failure to respond to non-invasive conservative therapy.
- The documentation contains conflicting information regarding the type of injection performed on 12-8-21. It is unclear whether the 12-8-21 lumbar medial branch block was diagnostic or therapeutic.

Facet Checklist (Not All-Inclusive)

❑ Moderate to severe pain for 3 months	❑ Do the procedure notes/office notes have conflicting information?
❑ Failure to respond to non-invasive conservative therapy	❑ Is it clear whether the injection is therapeutic or diagnostic?
❑ Is the chronic pain predominantly axial?	❑ Pre procedure pain assessment present
❑ Is there a disability scale for baseline functional assessment?	❑ Post procedure pain assessment present

Documentation Improvement

Conservative Treatment

- **Epidural Definition**
  - Conservative Therapy – Consists of an appropriate combination of medication (for example, non-steroidal anti-inflammatory [NSAIDs], analgesics, etc.) in addition to physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT), home exercise program, or other interventions based on the individual's specific presentation, physical findings, and imaging results.

- **Facet Definition**
  - Non-invasive conservative management – The use of nonsteroidal anti-inflammatory drugs (NSAIDs) acetaminophen, physical therapy, acupuncture (applies to only chronic low back pain), or spinal manipulation. This management should include the application a biopsychosocial treatment technique.

What Conservative Treatment Was Tried and Failed?

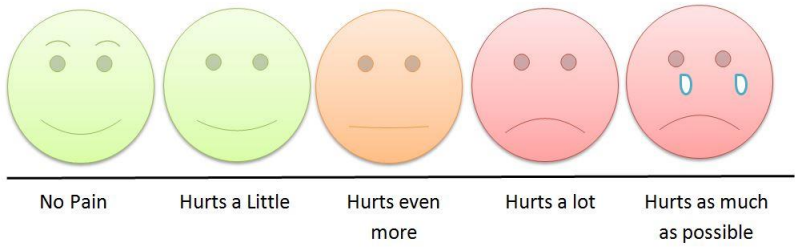
- Medications
  - What was the medication?
  - How long was it tried?
  - What was the outcome?
  - If the patient could not take a medication, document why the medication was contraindicated.
- Rest/activity modification
  - Did this help the pain?
- Physical Therapy
  - What body part received the therapy?
  - How long was the therapy?
  - Did therapy help even transiently?
  - Did the patient participate in a home exercise program?
- Electrical Stimulation
  - TENS
  - PENS

Procedure Documentation

- Pain score before and after MBB
- Pain score before and after SI Joint
- ESI — % relief pre and post injection
- How much relief?
  - 80% consistent relief for 12 hours with gradual return
  - 75% consistent relief for 5 months
  - Leg pain % vs back pain %

Functional improvement

- What painful movements can be performed that were not able to be performed before procedure?
- Sweeping, mopping, combing hair, can walk to mailbox



Procedure Relief- MBB

- "He had >90% relief and could walk further without pain. This was the best he's felt in years."

Duration of relief missing

- "Margaret had near 100% relief from her MBB."

Duration of relief missing. Functional improvement missing

- "Overall, patient states that she got at least 70% improvement in her left-sided neck pain from the procedure."

Criteria for RFA not met. RFA was still performed.

Documentation

- Modifying factors
  - What makes pain worse?
    - Flexion, extension, lateral bending
    - Walking, sitting
- Do medications help their pain?
  - Temporarily?

Functionality

- Is the patient still working?
- Are activities of daily (ADL) affected?
  - If so, specify what the patient cannot accomplish
  - After procedure was the patient able to perform these ADL's

New SI Joint Procedures LCD and Article

Effective March 19, 2023

- CGS
- NGS
- Noridian
- Palmetto
- WPS

SI Joint Policy

- **A. SIJIs** will be considered medically reasonable and necessary when all the following requirements are met:
  1. Moderate to severe LBP primarily experienced over the anatomical location of the SIJs between the upper level of the iliac crests and the gluteal fold, **AND**
  2. LBP duration of at least 3 months, **AND**
  3. LBP below L5 without radiculopathy, **AND**
  4. Clinical findings and/or imaging studies do not suggest any other diagnosed or obvious cause of the lumbosacral pain (such as central spinal stenosis with neurogenic claudication/myelopathy, foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, or pain related to spinal instrumentation), **AND**
  5. At least 3 positive findings with provocative maneuvers: FABER, Gaenslen, Thigh Thrust or Posterior Shear, SI Compression, SI Distraction and Yeoman Tests,[3,4] **AND**
  6. LBP persists despite a minimum of 4 weeks of conservative therapies.[5]

Diagnostic SIJIs

Diagnostic SIJI is used to determine if the etiology of pain is from the SIJ complex.[3]

Diagnostic SIJI are considered reasonable and necessary for patients who meet ALL the following criteria:

1. The patient must meet the above criteria for Covered Indications for SIJI, **AND**
2. The SIJIs must be performed under computed tomography (CT) or fluoroscopy image guidance with contrast, except ultrasound guidance may be considered reasonable and necessary when there is a documented contrast allergy or pregnancy, since the accuracy with ultrasound guidance is inferior to fluoroscopic guidance,[6] **AND**
3. **SIJI are not performed with other musculoskeletal injections in the lumbosacral spine, AND**

Diagnostic SIJIs

3. The documentation should show direct causal benefit from the SIJI and not from other musculoskeletal injections or treatments, **AND**
4. The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI (a positive diagnostic response is defined as ≥75% sustained and constant pain relief for the duration of the local anesthetic and ≥75% sustained and constant pain relief for the duration of the anti-inflammatory steroid) was measured by the SAME pain scale* at baseline.
    - The measurements of pain must be taken pre-injection on the day of the SIJI, post-intervention on the day of the injection, and the days following the injection to substantiate and corroborate the pain scores consistent with the pain relief for the duration of the local anesthetic and/or steroid used.

Limitation: No more than 2 diagnostic joint sessions, unilateral or bilateral.

- To clarify, 2 unilateral sessions, if performed on 1 side at 1 session and on the opposite side at a different session, would meet the limitation of 2 diagnostic sessions.

Therapeutic SIJI

Therapeutic SIJI will be considered medically reasonable and necessary for patients who meet **ALL** the following criteria:

1. The patient must meet the above criteria of Covered Indications for SIJI, **AND**
2. The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI
   - (a positive diagnostic response is defined as ≥75% sustained and constant pain relief for the duration of the local anesthetic and ≥75% sustained and constant pain relief for the duration of the anti-inflammatory steroid) was measured by the SAME pain scale* at baseline.
   - The measurements of pain were taken pre-injection on the day of the diagnostic SIJI, post-intervention on the day of the diagnostic injection, and
   - the days following the diagnostic SIJI to substantiate and corroborate consistent pain relief for the duration of the local anesthetic and/or steroid used, **AND**

Therapeutic SIJI

3. Subsequent therapeutic SIJI are considered medically reasonable and necessary when the subsequent SIJI are provided at the same anatomic site as therapeutic SIJI, **AND**
    - the therapeutic SIJI produced at least consistent 50% pain relief **or** at least 50% consistent improvement in the ability to perform previously painful movements and activities of daily living (ADLs) for at least 3 months from the proximate therapeutic SIJI procedure and compared to baseline measurements for ADLS and painful movements or pain relief using the same pain scale* **AND**
4. The SIJIs must be performed under CT or fluoroscopy image guidance with contrast, except ultrasound guidance may be considered reasonable and necessary when there is a documented contrast allergy or pregnancy, since the accuracy with ultrasound guidance is inferior to fluoroscopic guidance.[6]

Limitation: No more than 4 therapeutic SIJI sessions, unilateral or bilateral, will be reimbursed per rolling 12 months.

To clarify, a therapeutic SIJI session if performed on 1 side first and then on the opposite side at a different session would qualify as 2 sessions for the limitation of 4 therapeutic SIJ sessions per rolling 12 months.

SI Denervation

- **SIJ Denervation** (also called Radiofrequency Ablation or RFA) is not considered reasonable and necessary.
- *Note: The scales used to measure of pain and/or disability must be documented in the medical record. Acceptable scales include, but are not limited to: verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry LBP Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

SI Requirements

- The SIJI must be performed under CT or fluoroscopy image guidance with contrast, unless the patient has a documented contrast allergy or pregnancy where ultrasound guidance without contrast may be considered.[6]
- The SIJ procedure(s) should be performed in conjunction with conservative treatments.[7]
- Patient should be part of an ongoing, and be actively participating in a rehabilitation program, home exercise program or functional restoration program.[8,9]
- SIJ primary index pain must be measured prior to the injection at the beginning of the session.
- The post procedure pain level must be measured after the SIJI at the conclusion of the session.
- SIJI may be performed unilateral or bilateral if clinically indicated within the same session.
- The documentation must have the radiographic films (i.e., fluoroscopy images) of the procedure in at least 2 views (i.e., the pre and post contrast injection views in the AP and oblique planes) to confirm intraarticular injection of contrast and the treatment agent(s) used.

SI Requirements

- When documenting the percentage of pain relief from the primary (index) pain compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and/or a nonspecific statement of the duration of pain relief.
  - The documentation should include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the SAME pain scale* used at baseline.
- When documenting the ability to perform previously painful movements and ADLs it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and ADLs.
  - The documentation should include a functional assessment to show clinically meaningful improvement with painful movements and ADLs, if this metric is used to justify the efficacy of the SIJI procedure. Providers should use established and measurable goals and objective scales to assess functionality and ADLs measures.

SI Limitations

1. Injections performed without radiographic image guidance are not considered reasonable and necessary.[6]
2. A SIJI involves the use of an anesthetic, corticosteroid, and contrast agent and does not include injections of biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.) and/or any other injectates.
3. It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks, trigger point injections, etc.) during the same session as SIJIs and during the post SIJI efficacy assessment period.
4. Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for SIJIs, and therefore, not considered medically reasonable and necessary.[10] Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice.[9]
5. SIJIs to treat non-specific LBP, axial spine pain primary above the level of L5, complex regional pain syndrome (CRPS), widespread diffuse pain, chronic pain syndrome, and pain from neuropathy are considered investigational, and therefore, are not considered medically reasonable and necessary.

SI Limitations

6. SIJIs used as part of a series of lumbar spine and musculoskeletal injections to treat nonspecific or chronic LBP is not considered reasonable and necessary.
7. In patients with implanted electrical devices, (i.e., spinal cord stimulation, peripheral nerve stimulation, cardiac devices, etc.) and intrathecal pump delivery devices, providers should follow manufacturer instructions and extra planning as indicated to ensure safety of the procedure.
8. Patients with coexisting psychological conditions or depression related illness should be treated and stabilized prior to proceeding with interventional procedures.[11] Multidisciplinary biopsychosocial rehabilitation principles should be provided to these patients.

SI Limitations

1. It generally would not be considered medically reasonable and necessary for treatment with SIJIs to extend beyond 12 months. Frequent continuation of SIJIs over 12 months may trigger a focused medical review. Use beyond 12 months requires the following:
    a. Pain is severe enough to cause a significant degree of functional disability or vocational disability and providers use established and measurable goals and objective scales to assess functionality and ADLs measures.
    b. SIJIs provides at least 50% sustained and consistent improvement of pain and/or 50% sustained and consistent objective improvement in function (using same scale as baseline) for at least 3 months.
    c. Rationale for the continuation of SIJIs, including but not limited to, patients who are high-risk surgical candidates, the patient does not desire surgery, and/or the recurrence of pain in the same location was sustained and consistently relieved with the SIJIs for at least 3 months.
    d. The primary care provider should be notified regarding continuation of procedures and prolonged repeat steroid use to allow for systematic care delivery treatment surveillance and multidisciplinary biopsychosocial rehabilitation (MBR).

SI Limitations

3. A subsequent diagnostic SIJI is not reasonable and necessary when the initial diagnostic block does not produce a positive response of ≥ 75% pain reduction.
4. A subsequent therapeutic SIJI is not reasonable and necessary when the proximate SIJI did not provide at least a consistent 50% pain relief or at least a 50% consistent improvement in the ability to perform previously painful movements and ADLs for at least 3 months compared to baseline objective measurements for ADLS and painful movements or pain relief using the same pain scale.*

Proposed Multi-jurisdictional LCD

Draft Policy
CGS
Noridian
Palmetto
WPS

Medically Necessary Urine Drug Testing

- Potential benefits
  - Identify unauthorized substances – illicit street drugs or non-prescribed medications
  - Detect presence of prescribed medication as evidence of adherence and potential hoarding or diversion
  - Assist with therapeutic decision making

Purpose of UDT- PROPOSED LCD

- Presumptive UDT may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions.
- Definitive UDT is considered reasonable and necessary when the clinical information supplied supports the definitive testing as in:
  - Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;
  - Definitively identify specific drugs in a large family of drugs;
  - Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
  - Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
  - Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
  - Rule out an error as the cause of a presumptive UDT result;
  - Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
  - Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Presumptive UDT Panels

- Presumptive UDT typically involves testing for multiple analytes based on the specific beneficiary's clinical history and risk assessment and must be documented in the medical record.
  - May be ordered as a panel and billed a "Per Patient encounter" regardless of the number of analytes tested.

Definitive UDT–PROPOSED LCD

- Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions
  - **To establish that a test is reasonable and necessary, the clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record.**
- Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use, clinical findings, and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice.
  - **Definitive UDT orders should be individualized based on clinical history and risk assessment and must be documented in the medical record.**

Frequency—Proposed LCD

- National pain organizations, physician societies, and the Federation of State Medical Boards[15] recommend a practical management approach to definitive UDT for COT.
- The number of UDTs billed over time beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record.

Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 365 days for prescribed medications, non-prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 180 days for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 3 times each in a rolling 90 days for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

COT Baseline Testing—PROPOSED POLICY

- Depending on the patient's specific circumstances, initial presumptive and/or definitive COT patient testing may include
  - amphetamine/ methamphetamine,
  - barbiturates,
  - benzodiazepines,
  - cocaine,
  - methadone,
  - oxycodone,
  - tricyclic antidepressants,
  - tetrahydrocannabinol,
  - opioids,
  - opiates,
  - heroin, and
  - synthetic/analog or "designer" drugs.

Chronic Opioid Therapy Monitoring Testing—PROPOSED POLICY

COT Monitoring Testing:

1. Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern[16].
    a. As part of the clinical evaluation of the patient, the provider should inquire about prescription compliance and potential issues of abuse or diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication[16].
    b. The number of UDTs billed over time must be based on the individual's risk potential[1].
2. The clinician should perform random UDT at random intervals, in order to properly monitor a patient[17]. UDT testing does not have to be associated with an office visit.
3. Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

Risk Stratification

Opioid Risk Tool:

- The patient's risk category must be clearly defined in the medical record and is essential in determining number of UDTs billed over time and medical necessity.

- This TOOL is to be used as a suggestion for defining Risk and this document is just an example and other tools accepted by the Opioid Use treating community may be used. Example, accepted by SAMHSA (Substance Abuse and Mental Health Services Administration)

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
   - To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
   - To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.
2. When medical record documentation that is individualized for a particular patient satisfies medical necessity requirements found elsewhere in this LCD (e.g., risk assessment, frequency), direct to definitive UDT without a presumptive UDT may be reasonable and necessary.

Other Covered Services

3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
   - The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
   - Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
   - When there is an unexpected negative presumptive UDT result, and it is clinically imperative to know if it is truly positive or negative; the medical record should state such.
4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Billing and Coding Article – PROPOSED

- A claim submitted without a valid ICD-10-CM diagnosis code will be returned to the provider as an incomplete claim under Section 1833(e) of the Social Security Act.
- The diagnosis code(s) must best describe the patient's condition for which the service was performed.
  - For diagnostic tests, report the result of the test if known; otherwise the symptoms prompting the performance of the test should be reported.

Comment Period Ends …

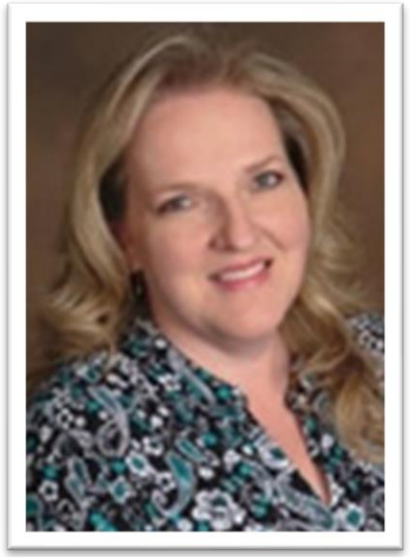
- CGS June 10
- Noridian June 12
- Palmetto June 10
- WPS July 15

See your MAC for a link to the proposed LCD and billing article

Resources

- Prior authorization guide: www.cms.gov/files/document/opd-operational-guide.pdf
- CMS 100-20, Change Request 13016: www.cms.gov/files/document/r11753otn.pdf
- Proposed LCDs in alphabetical order: www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=all

Questions & Answers



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