Jurisdiction 15

Open Draft/LCD Meeting

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CGS Administrators | A/B MAC Jurisdiction 15

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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This publication 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.

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Draft Local Coverage Determinations (LCDs)

Proposed Policies and Schedule/Tentative Times for Oct 25th (KY) and Oct 26th (OH)

- 4-4:30pm EST
  - Sacroiliac Joint Injections and Procedures DL39383/ DA59154
- 4:30-5pm EST
  - Urine Drug Testing DL36029/DA56818
  - Transtelephonic Spirometry DL34541/DA56808
  - Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin DL39434/DA59215
  - MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis DL39427/ A58713
  - MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma DL39389/DA59163
- 5-5:30pm EST
  - Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL) DL36690/DA56696

Sacroiliac Joint Injections and Procedures

A multi-jurisdictional CAC meeting was held as part of this policy development on Mar 10, 2022, via teleconference hosted by:

- National Government Services
- CGS Administrators
- Noridian Healthcare Solutions
- Palmetto GBA
- Wisconsin Physician Service Insurance Corporation

Recording/transcript available at https://www.cgsmedicare.com/partb/medicalpolicy/lcd_discussion_recordings.html

Sacroiliac Joint Injections and Procedures

- Sacroiliac joint is uniquely challenging as it is a complex structure, and the exact pattern of innervation is unclear. Pain from the SIJ joint can be variable including severe pain.
- The literature for sacroiliac joint pain is limited by few placebo-controlled randomized trials, lack of long-term data, inconsistencies in diagnostic criteria, assessment of outcomes, and technique of procedures resulting in high heterogeneity between the studies.
- Careful evaluation of the medical literature and utilization of the best available evidence serves as the basis for our determinations in coverage and guidelines.
- The LCD coverage and guidelines were supplemented with the knowledge shared from our subject matter expert panel.

Sacroiliac Joint Injections (SIJI)

Considered medically reasonable and necessary when all the following are met:

- Moderate to severe low back pain primarily experienced over the anatomical location of the SI joints between the upper level of the iliac crests and the gluteal fold, AND
- Low back pain duration of at least three (3) months, AND
- Low back pain below L5 without radiculopathy, AND
- Clinical findings and/or imaging studies do not suggest any other diagnosed or obvious cause of the lumbosacral, AND
- At least three positive findings with provocative maneuvers: FABER, Gaenslen, Thigh Thrust or Posterior Shear, SI Compression, SI Distraction and Yeoman Tests, AND
- Low back pain persists despite a minimum of four weeks of conservative therapies.

Diagnostic Sacroiliac Joint Injections

Diagnostic SIJI is used to determine if the etiology of pain is from the sacroiliac joint complex and are considered reasonable and necessary for patients who meet the criteria above AND all the following criteria:

- The SI joint injections must be performed under CT or fluoroscopy image guidance with contrast (except ultrasound guidance may be considered when there is a documented contrast allergy or pregnancy), AND
- SI joint injection are not performed with other musculoskeletal injections in the spine, AND
- The documentation should show direct causal benefit from the SI joint injection and not from other musculoskeletal injections or treatments, AND
- 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.

Diagnostic Sacroiliac Joint Injections

- No more than two (2) diagnostic joint sessions, unilateral or bilateral.
- KX modifier requirements:
  - The KX modifier should be appended to the line for all diagnostic injections.
  - The KX modifier will only be used for the initial diagnostic injections.
  - Repeat diagnostic injections beyond the first one or two required to confirm the diagnosis, after beginning treatment are not reasonable and necessary.
- A subsequent diagnostic SIJI is not reasonable and necessary when the initial diagnostic block does not produce a positive response of ≥ 75% pain reduction.

Pain Scales

- Pain scale must be obtained at:
  - Baseline: **pre-injection** on the day of the SIJ injection, and
  - **Post-intervention 1** on the day of the injection, and
  - **Post-intervention 2** - 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.
- 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 Low Back Pain 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.

Therapeutic Sacroiliac Joint Injections

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

- The patient must meet the above criteria of Covered Indications for SIJI, AND
- 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 SIJ injection, post-intervention on the day of the diagnostic injection, and the days following the diagnostic SIJ injection to substantiate and corroborate consistent pain relief for the duration of the local anesthetic and/or steroid used.

Therapeutic Sacroiliac Joint Injections

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 three (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. Subsequent blocks not meeting this requirement are not considered R&N.
- The SI joint injections 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)
- No more than **four (4)** therapeutic SIJI sessions, unilateral or bilateral, will be reimbursed per rolling 12 months.

SIJ Denervation

- SIJ Denervation (also called Radiofrequency Ablation or RFA) is considered investigational and therefore not reasonable and necessary.

Requirements

- The SIJ procedure(s) should be performed in conjunction with conservative treatments.
- Patient should be part of an ongoing, and be actively participating in a rehabilitation program, home exercise program or functional restoration program.
- SIJI may be performed unilateral or bilateral if clinically indicated within the same session.

Documentation

- The documentation must have the radiographic films (i.e., fluoroscopy images) of the procedure in at least two (2) views
- 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. For functional assessment must show clinically material improvement with painful movements and ADLs.

Limitations

- 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.
- 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 SIJs procedures.
- SIJIs to treat non-specific low back pain (LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, chronic pain syndrome, and pain from neuropathy are considered investigational.
- SIJIs used as part of a series of lumbar spine and musculoskeletal injections to treat nonspecific or chronic low backpain are not considered reasonable and necessary.
- Patients with coexisting psychological conditions or depression related illness should be treated and stabilized prior to proceeding with interventional procedures. Multidisciplinary biopsychosocial rehabilitation principles should be provided to these patients.

Limitations (Treatment beyond 12 months)

It generally would not be considered medically reasonable and necessary for treatment with SIJIs to extend beyond 12 months. Use beyond 12 months requires the following:

a. Pain is severe enough to cause a significant degree of functional disability or vocational disability measured by objective scales

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 three (3) months.

c. Rationale for the continuation of SIJIs including but not limited to patient 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 three (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).

Transtelephonic Spirometry

- Changes based on LCD reconsideration
- Literature to support role in monitoring for lung transplant recipients reviewed and coverage criteria added to policy.
- Home spirometry and telespirometry is considered experimental and investigational for all other indications (asthma, idiopathic pulmonary fibrosis, and persons with other chronic pulmonary diseases/disorders (e.g., emphysema)) because there is a lack of evidence that it will improve the care of persons with these disorders.

Transtelephonic Spirometry

Home spirometry and telespirometry is considered reasonable and medically necessary for lung transplant recipients when the following is met:

1. Lung transplant patient
2. Adherence to home spirometry measurements of ≥80%. This is defined by transmission of data at least 80% of the time.
3. If patient is non-compliant* than they are not eligible for further home spirometry services.

*Non-compliance is defined as no measurements or transmitted for 7 consecutive days x 2. If they are non-compliant for one week the coordinator can reach out and offer education. If non-compliance continues (no measurement for 7 days) than the service will no longer be eligible for coverage.

Urine Drug Testing

Summary of changes:

- Clarification of when the defined test are covered
  - Presumptive/qualitative is covered when medically necessary to immediately determine the presence or absence of drugs or drug classes in a urine sample (positive or negative results and available immediately)
  - 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.

Urine Drug Testing

- Definitive/Quantitative/Confirmation – Covered when clinically indicated and medically reasonable and necessary to identify specific medications, illicit substances, and metabolites (reported in concentration).
  - 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.

Urine Drug Testing

- Definitive testing continued….
  - 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.
  - 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.

Urine Drug Testing

- Point of Care Testing (POCT)- Covered when medically necessary by clinicians caring for the beneficiary for immediate test results for the immediate management of the beneficiary; available when the beneficiary and physician are in the same location

- Maximum number of allowed changed to rolling days (1 week is rolling 7 days)

- Blanket orders (same orders for all patients in the practice) is non-covered

Urine Drug Testing

- 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.
- Risk assessment is a widely accepted standard by expert treating entities to be used in clinical treatments and follow-up.
- The provider shall clearly define risk assessment as part of the reasonable and necessary criteria for UDT.
- Opioid Risk Tool (ORT) added to determine risk category added to LCD as suggested risk assessment tool

Urine Drug Testing

- The routine use of no more than 14 classes of drugs based on DEA and AACLM clinical guidelines is not supported.

The following codes are Non-Covered by Medicare:

CPT/HCPCS Codes	Short Description
80320 – 80377	Drug screen quantalcohols- Drug/substance nos 7/more
G0482	Drug test def 15-21 classes
G0483	Drug test def 22+ classes
G0659	Drug test def simple all cl

Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin

NCD 110.23 Stem Cell Transplantation includes allogenic transplantation for certain conditions. Per the NCD, “All other indications for stem cell transplantation not otherwise noted above as covered or non-covered remain at local Medicare Administrative Contractor discretion.”

Allogenic hematopoietic cell transplant is considered reasonable and necessary when:

1. Patient has primary refractory or relapse of Hodgkin's or non-Hodgkin's lymphoma with B-cell or T-cell origin AND
2. Pre-transplantation assessment indicates good function status, low-comorbidities and patient is candidate for transplantation based on risk assessment AND
3. There are no other treatment options available with curative intent

Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin

- Emerging evidence support the role of allogenic hematopoietic cell transplant for primary or refractory Hodgkin's or non-Hodgkin's lymphoma when there are no other treatment options with a curative intent, pre- transplant assessment indicates a high probability of success with the transplantation.
- Multiple tools to perform this assessment are available and include assessment of the patient’s functional status, co-morbidities, and other factors for candidacy for transplantation.
- While age was considered a contraindication in the past evidence supports removal of age restrictions as there have been improved outcome in appropriately selected patients over age 70.

MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis

- Current molecular biomarker tests to guide targeted therapy selection in Rheumatoid Arthritis (RA) are non-covered
- There is currently no certain way to predict which patients will respond to the various available therapies for RA. Numerous molecular biomarker tests have been proposed that can predict response (or non-response) to certain classes or multiple classes of drugs in RA treatment. Some are based on genetic markers found in blood, some on genetic markers in combination with clinical and laboratory factors, and others on transcriptomics within the synovium.
- Despite this need clinical validity has not yet been established for the current evaluated molecular biomarker tests that guide targeted therapy selection in RA

MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma

This Medicare contractor will provide limited coverage for molecular Deoxyribonucleic acid (DNA)/Ribonucleic acid (RNA) assays that aid in the diagnosis or exclusion of melanoma from a biopsy when ALL the following clinical conditions are met:

- The test is ordered by a board-certified or board-eligible dermatopathologist
- The specimen is a primary (non-metastatic, non-re-excision specimen) cutaneous melanocytic neoplasm for which the diagnosis is equivocal/uncertain
- The specimen includes an area representative of the lesion or portion of the lesion that is suspicious for malignancy
- The patient may be subjected to additional intervention, such as re-excision and/or sentinel lymph node biopsy, as a result of the diagnostic uncertainty

MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma

- The patient has not been tested with the same or similar assay for the same clinical indication
- The test is validated for use in the intended-use population and is performed according to its stated intended-use
- The test demonstrates Analytical and Clinical Validity (AV and CV) and Clinical Utility (CU) and undergoes a technical assessment (TA) by MolDx® to demonstrate compliance of the service with this policy

The myPath® Melanoma and DiffDx™-Melanoma assays are only validated for primary cutaneous neoplasms, precluding testing of metastases, non-cutaneous melanomas, and re-excision specimens. Tests that demonstrate similar indicated uses and equivalent or superior performance to covered tests may similarly be covered under this policy.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Skin substitute defined:

Per the Current Procedural Terminology (CPT®) codebook definition, skin substitute grafts include non-autologous human skin (dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), nonhuman skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth.

Skin substitute graft application codes are not to be reported for application of non-graft wound dressings (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Skin substitute Grafts

In order to qualify as skin substitute graft the product must be:

1. Non-autologous human skin OR
2. Non-human skin substitute grafts (“i.e., xenograft”), OR
3. form a sheet scaffolding for skin growth

The graft is intended to remain on the recipient and grow in place or have the recipient’s cells grow into the implanted graft material. Products that require regular replacement (i.e., weekly) do not meet this definition.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

- This is revision to policy previously titled ‘Wound Application of Cellular and/or Tissue Based Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers.’
- The ‘History/Background and/or General Information’ section of the LCD has been revised to clearly describe the services addressed in the LCD and additional regulatory information has been included for skin substitute products.
- The following sections of the LCD have been reworded and revised to be consistent with the evidence: ‘Covered Indications’ and ‘Limitations’. The following sections were added: ‘Provider Qualifications’, ‘Summary of Evidence’, ‘Societal Input’ and ‘Analysis of Evidence’.
- Documentation Requirements are located in the associated billing and coding article (DA56696).
- The Utilization Guidelines have been incorporated into the ‘Limitations’ section.
- The ‘Bibliography’ section has been updated to include all literature utilized in the development of this LCD.
- Formatting changes have been made throughout the LCD.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Coverage

If the patient meets all the criteria as outlined in this LCD, application of a skin substitute graft for lower extremity DFU or VLU is considered medically reasonable and necessary for the following:

1. The presence of a chronic, non-infected DFU having failed to respond to documented conservative wound care measures for greater than four weeks with documented compliance.
2. The presence of a chronic, non-infected VLU having failed to respond to documented conservative wound care measures for greater than four weeks with documented compliance.
    - Conservative wound care measures defined in LCD
3. An implemented treatment plan demonstrating all of the following: debridement, offloading for DFUs and some form of compression for VLUs, infection control, management of exudate, smoking cessation actions.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Coverage

4. The skin substitute graft is applied to an ulcer that has failed to respond (defined in LCD) to documented conservative wound care measures.
5. The medical record documentation addresses **why** the wound has failed to respond to standard wound care treatment of greater than 4 weeks and includes **specific interventions** that have failed.
6. Skin substitute grafts utilized per the approved FDA intended use.
7. The patient is under the care of a qualified physician/NPP for their underlying chronic condition.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Limitations

These are not considered reasonable and necessary (therefore non-covered):

1. Exceeding maximum of 4 applications of skin substitute graph product within an episode of skin replacement surgery defined as 12 weeks from the first application and consistent with product labeling. Must use fewest repeat applications and amount required to heal the wound.
2. Switching skin substitute graft products in a 12-week episode of skin replacement surgery
3. Use of application of a skin substitute graft product beyond 12-weeks.
4. Repeat applications of skin substitute grafts when a previous application was unsuccessful as defined in policy.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Limitations

5. Application of skin substitute grafts in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications.
6. Use of surgical preparation services (for example, debridement), in conjunction with routine, simple and/or repeat skin replacement surgery with a skin substitute graft.
7. Excessive wastage (discarded amount).
    - The skin substitute graft must be used in an efficient manner utilizing the smallest package size available for purchase from the manufacturer that could provide the appropriate amount for the patient.
8. All liquid skin substitute products for wound care.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Frequency

- There is paucity of evidence to address how frequently skin substitutes should be reapplied.
- One study reports median time-to-heal of 16 weeks using an average of 1.24 applications of NEOX Wound Allograft. Couture reported using an average of 3.43 NEOX applications with an average healing time of 5.53 weeks in a single-center retrospective study.
- A retrospective chart review by Raphael reported median time to heal 13.79 weeks with an average 1.68 applications.
- Armstrong and colleagues presented a retrospective analysis at the 2021 Wounds UK annual Conference reporting skin substitutes were applied every 7-14 days.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

- An extensive variety of wound care products are available for providers to select from when treating chronic wounds. Many of these products may simulate or substitute for some aspect of the skin's structure and function to promote healing and wound closure. The materials used to create these products may be derived from human or animal tissue and may undergo extensive or minimal processing to generate the finished product. The degree of processing and the source of the material used in the product also governs which regulatory pathway may be required before the product may be marketed.
- The LCD reviews the various pathways.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

- Coverage will be provided for products in the associated billing and coding guideline meeting the necessary FDA regulatory requirements as of publication. Each product has specific designated approved usage.
- New products will be considered for coverage if meeting the regulatory requirements and criteria. Satisfactory evidence of FDA regulatory requirements include:
  1. A copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA),
  2. A listing of the drug or biological in the FDA's "Approved Drug Products" or "FDA Drug and Device Product Approvals",
  3. A copy of the manufacturer's package insert approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it, or
  4. Information from the FDA's Website.

Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

- For skin substitutes classified as HCT/Ps, a letter from the FDA indicating that the HCT/P has met regulatory guidance is acceptable evidence of the FDA regulatory compliance for HCT/Ps regulated under section 361 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act.
- It is recommended that the manufacturer of the particular skin substitute graft or CTP product obtain the appropriate information and send to the MAC along with evidence-based literature, if available. Once this information has been received by the MAC, the product will be considered for coverage and placed into the appropriate Code Group in the associated article.

Open Comment Period

JURISDICTION 15 **DRAFT LCD COMMENT SUBMISSION FORM**

METHODS FOR SUBMISSION OF DRAFT LCD COMMENT FORM

Draft LCD Comment submissions may be sent via one of three methods: Email (preferred), fax, or hard copy by mail. Pertinent information is listed below for each of the three methods.

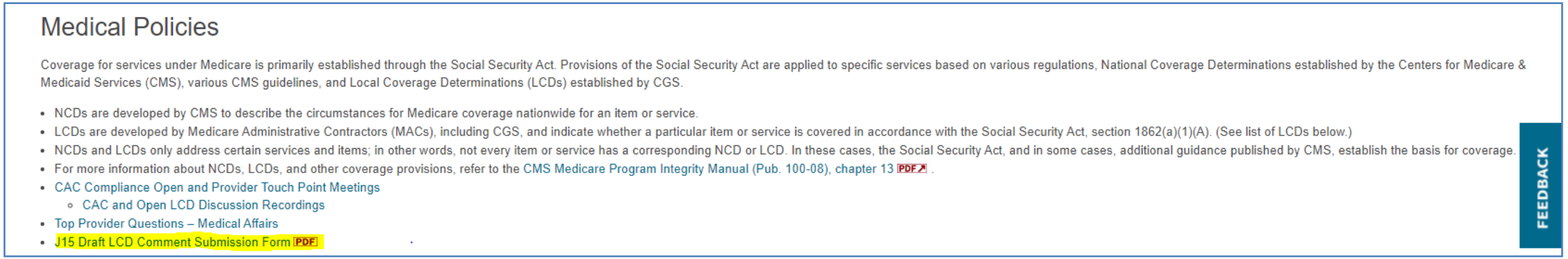
Type	Contact	Details
Email to (preferred method):	CMD.INQUIRY@cgsadmin.com	• Electronic requests should be sent with "Draft LCD Comment Submission – [Name of LCD]" in the subject line. • If the attachment size for clinical citations exceeds 15 MB, the requestor must send the articles and supporting documents via multiple, smaller emails. • Please contact CMD.INQUIRY@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting a Draft LCD Comment form.
Fax to:	1.615.664.5971	Please address your fax cover sheet to: Draft LCD Comment Submission – [Name of Draft LCD] - Attn: Chief Medical Director
Mail to:	CGS Administrators, LLC Attn: Chief Medical Director J15 A/B MAC Draft LCD Comment 26 Century Blvd, STE ST610 Nashville, TN 37214-3685	N/A

Open Comment Period: Preferred Method

- Comment period for these policies is 10/6/22-11/20/22.
- To submit comments, go to: https://www.cgsmedicare.com/pdf/j15/j15_draft_lcd_comment_submission_form.pdf
- Complete the PDF form and send attachments to CMD.INQUIRY@cgsadmin.com
- Must provide supporting literature for the comments in full-text PDF
- Supporting literature must be published
  - In press and abstracts cannot be considered

Open Comment Period: Preferred Method

The comment link can be found on the CGS website under Medical Policies



Medical Policies

Coverage for services under Medicare is primarily established through the Social Security Act. Provisions of the Social Security Act are applied to specific services based on various regulations, National Coverage Determinations established by the Centers for Medicare & Medicaid Services (CMS), various CMS guidelines, and Local Coverage Determinations (LCDs) established by CGS.

- NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for an item or service.
- LCDs are developed by Medicare Administrative Contractors (MACs), including CGS, and indicate whether a particular item or service is covered in accordance with the Social Security Act, section 1862(a)(1)(A). (See list of LCDs below.)
- NCDs and LCDs only address certain services and items; in other words, not every item or service has a corresponding NCD or LCD. In these cases, the Social Security Act, and in some cases, additional guidance published by CMS, establish the basis for coverage.
- For more information about NCDs, LCDs, and other coverage provisions, refer to the CMS Medicare Program Integrity Manual (Pub. 100-08), chapter 13 PDF .
- CAC Compliance Open and Provider Touch Point Meetings
  - CAC and Open LCD Discussion Recordings
- Top Provider Questions – Medical Affairs
- J15 Draft LCD Comment Submission Form PDF

FEEDBACK

Jurisdiction 15

Open Draft/LCD Meeting

Thank you for joining us!

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