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Laboratory Compliance

10/4/2022

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Today's Presenters

- Provider Outreach and Education
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Objectives

- Recognize coding problems and issues and adopting appropriate claim submission management system
- Understand your compliance role in laboratory billing to reduce or eliminate improper claim submissions to prevent appeals, fraud and abuse from occurring

Agenda

- Introduction and Overview
- Clinical Laboratory Improvement Act
- Codes and Modifiers
- Medicare Coverage Database
- National Coverage Determinations
- Specimen Collections

Laboratory Types

- Clinical laboratory services
  - Clinical laboratory services involve examination of samples obtained from human body for interpretation of medical condition and to make decision for its prevention, diagnosis, and treatment
- Diagnostic laboratory services
  - Diagnostic lab services are different from simple clinical tests. Clinical tests require a pathologist and lab technician to run and interpret samples whereas, diagnostic tests require a physician or other certified professional to perform

Laboratory Types

- Just like type of lab services are different, types of labs themselves, are also different
- When working with primary physician, there may be some amount of lab testing
- If physician's office has a certified lab, providers may bill for significant number of lab procedures including E/M services

Laboratory Performing Lab Tests

- Independent laboratory
  - Operate independently out of physician's office, a hospital, or any external facility are termed as independent laboratories
- Physician office laboratory
  - Operate within physician's office, to perform testing procedures are referred to as physician office labs
- Clinical laboratory
  - Specialties utilize different biological tests to determine a patient's medical condition by using specimens obtained from them and also referred to as CLIA labs

Laboratory Performing Lab Tests

- Referring laboratory
  - Labs that receives specimen for testing purposes but further refers to sample for testing to different lab
- Reference laboratory
  - Labs that receive referred sample from referring laboratory are known as reference labs. They can also be considered as a type of physician office lab as they depend upon an external facility to perform testing
- Medicare-approved laboratory
  - Labs meet criteria laid down by Medicare, and are quite popular among providers. They also have CLIA certification which makes them first choice for referring labs, hospitals and other physician practices

Laboratory Written Orders

- All tests must have written order on file
- Only appropriate tests actually performed may be billed
- Unsigned physician orders or unsigned requisitions alone don't support physician intent to order
- Physicians should sign all orders for diagnostic services to avoid potential denials
- Attestation statements are unacceptable for unsigned physician orders or requisitions

Clinical Laboratory Improvement Act

Clinical Laboratory Improvement Act

- CLIA mandates and regulates laboratories that test patient specimens and ensure laboratories produce accurate and reliable test results
  - Certificate of Waiver
  - Certificate for Provider Performed Microscopy Procedures
  - Certificate of Registration
  - Certificate of Compliance
  - Certificate of Accreditation

CLIA Waived

- Waived laboratories must
  - Enroll in the CLIA program
  - Pay applicable certificate fees every two years
  - Follow manufacturer's test instructions
    - Enter CLIA in item 23
- Clinical Laboratory Improvement Amendments (CLIA)

80000-89999: Pathology/Laboratory Services

- 80047–80081: Organ or Disease Oriented Panels
- 80150–80299: Therapeutic Drug Assays
- 80305–80377: Drug Assay Procedures
- 80400–80439: Evocative/Suppression Testing Procedures
- 80500–80502: Clinical Pathology Consultations
- 81000–81099: Urinalysis Procedures
- 81105–81479: Molecular Pathology Procedures
- 81410–81471: Genomic Sequencing Procedures and Other Molecular Multi analyte Assays
- 81490–81599: Multi analyte Assays with Algorithmic Analyses
- 82009–84999: Chemistry Procedures

80000-89999: Pathology/Laboratory Services

- 85002–85999: Hematology and Coagulation
- 86000–86849: Immunology
- 85850–86999: Transfusion Medicine
- 87003–87999: Microbiology
- 88000–88099: Anatomic Pathology
- 88104–88199: Cytopathology
- 88230–88299: Cytogenetic Studies

80000-89999: Pathology/Laboratory Services

- 88300–88399: Surgical Pathology
- 88720–88749: In Vivo (Transcutaneous) Lab Procedures
- 89049–89240: Other Procedures
- 89250–89398: Reproductive Medicine Procedures
- 0001U–0017U: Proprietary Laboratory Analyses

Introduction and Overview

- Clinical laboratory services must be
  - Approved by provide specific type of test being performed
  - Ordered promptly by physician or qualified nonphysician practitioner treating patient
  - Reasonable and necessary

Introduction and Overview

- Outpatient clinical laboratory services are
  - Paid on fee schedule
  - Participating laboratory
  - Ordered by physician or qualified nonphysician practitioner
  - Must accept assignment
  - Neither annual deductible nor 20% coinsurance applies to
    - Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis
    - Specimen collection fees
    - Travel allowance related to laboratory tests (e.g., collecting specimen)

Medically Unlikely Edits and Correct Coding Initiative

CMS Official Website

Medically Unlikely Edits

- MUEs used by MACs, to reduce improper payment rate for Part B claims
- Maximum units of service provider report under most circumstances for a single beneficiary on a single date of service

MUE Adjudication Indicator: 1

- MUE Adjudication Indicator "1" indicates edit is claim line
  - Appropriate use of NCCI modifiers (e.g., 59, 76, 77, 91, anatomic) may be used to report same code on separate lines of claim
  - Medical records must support total units for date of service and use of modifiers

MUE Adjudication Indicator: 2

- MUE edits with MUE Adjudication Indicator "2" (Date of Service Edit: Policy)
  - MUE value is absolute date of service limit that may not be bypassed with modifier
  - MUE edit limits with an MAI of "2" have been rigorously reviewed within CMS
  - Units in excess of MUE value on date of service would be considered impossible because of code definition, anatomical consideration, CMS statute, regulation or sub-regulatory guidance

MUE Adjudication Indicator: 3

- MUE edits with MUE Adjudication Indicator "3" (Date of Service Edit: Clinical)
  - Medically highly unlikely more units than MUE value would ever be performed on same date of service; same patient
  - Quantity limits based on clinical benchmarks and criteria (e.g., nature of service, prescribing information) combined with data
  - MUE limits will be applied during claim processing

National Correct Coding Initiative

- CMS developed NCCI to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Part B claims
- Purpose of NCCI PTP edits is to prevent improper payment when incorrect code combinations are reported

Medicare Coverage Database and National Coverage Determinations

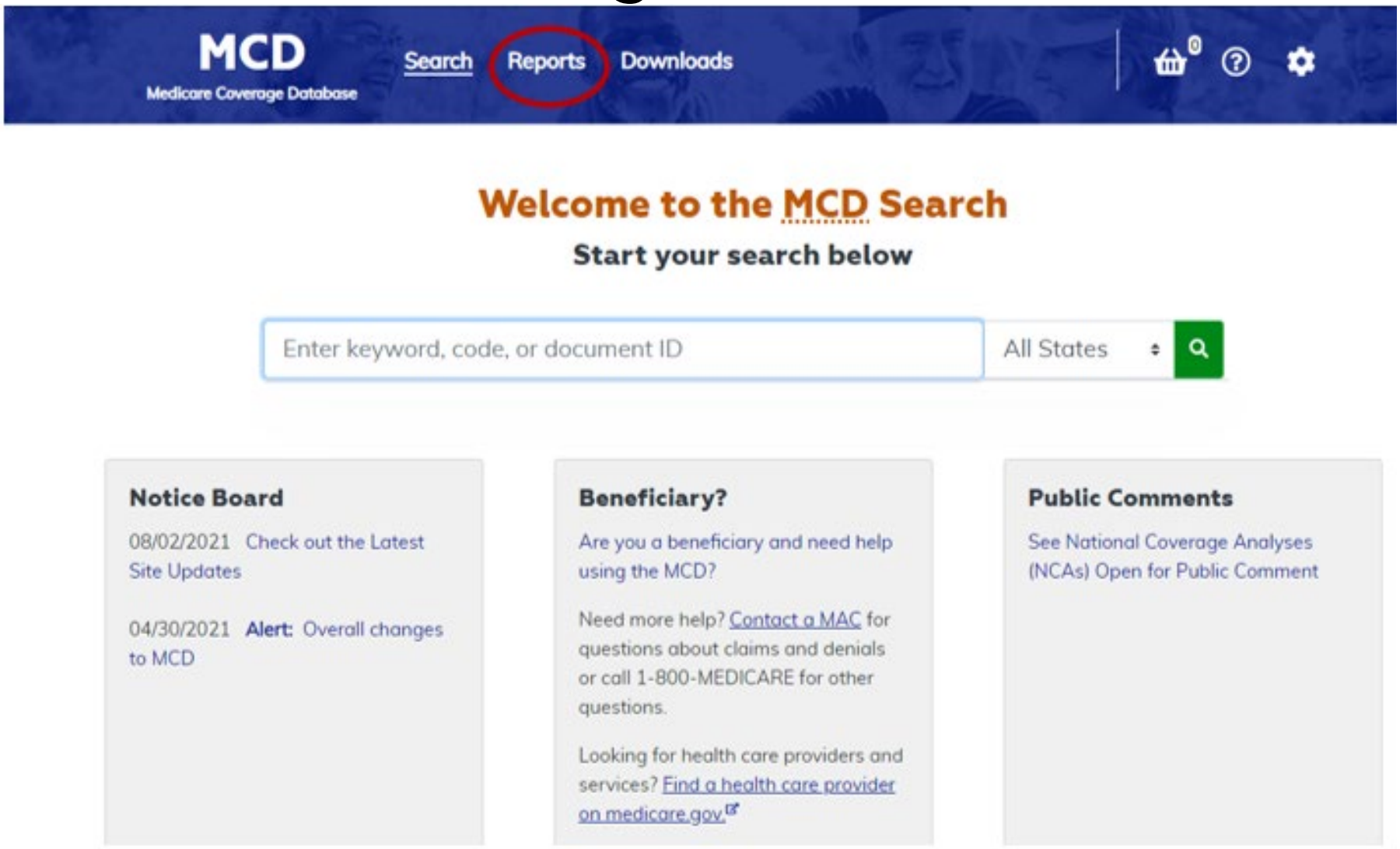
Medicare Coverage Database

- Contains all national coverage documents, Medicare coverage and general information
  - NCDs, National Coverage Analyses, Coding Analyses for Labs, Medicare Evidence Development & Coverage Advisory Committee meetings, and Medicare coverage guidance documents
- Database also include LCDs mandated at contractor level and those guidelines are only applicable to certain jurisdiction

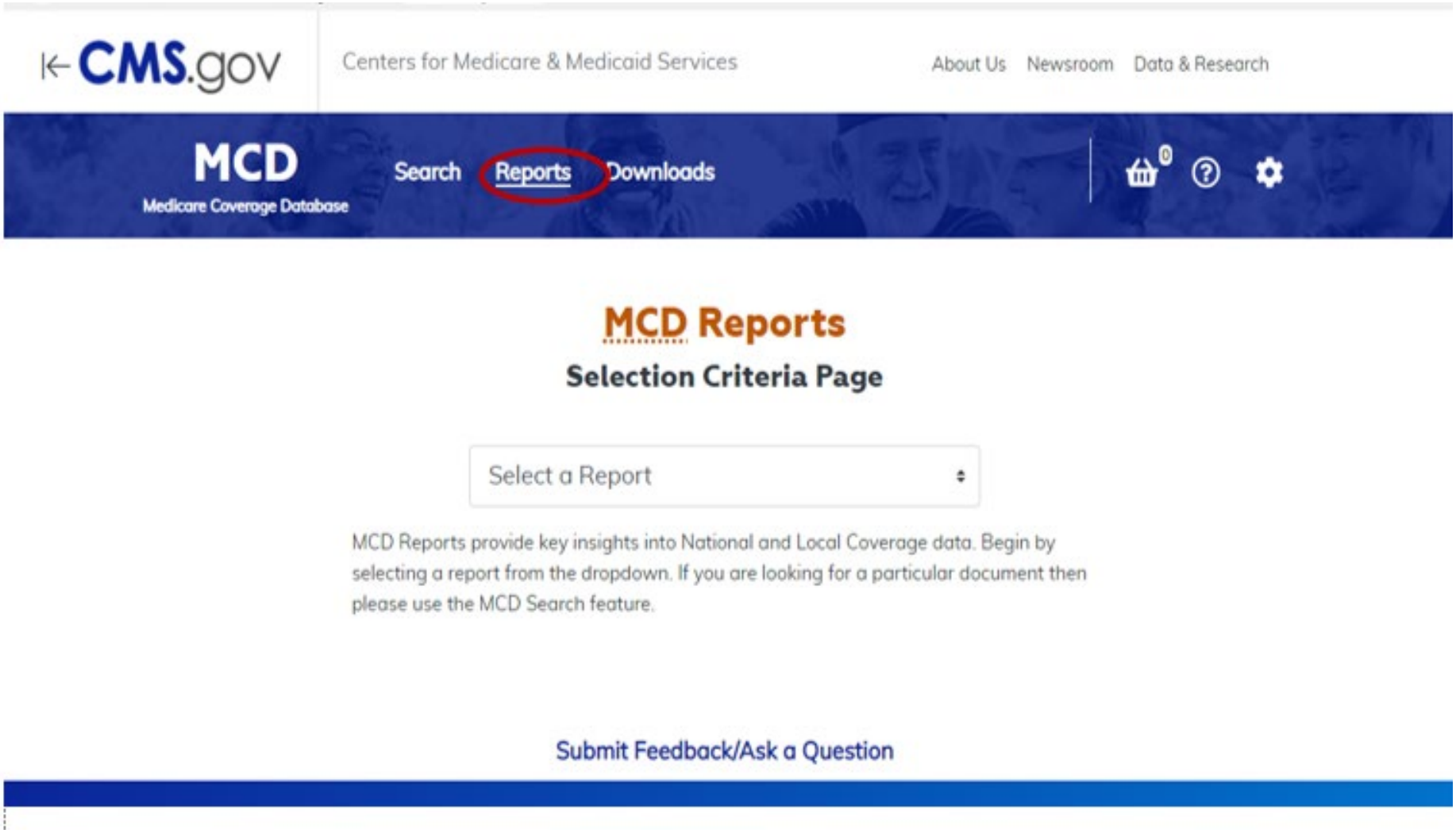
National Coverage Determinations

- NCDs are nationwide determination of whether Medicare will pay for service
- Developed by CMS to describe circumstances for Medicare coverage for specific medical service or procedure
- NCDs outline conditions for which service is considered to be covered or not covered and issues program instruction

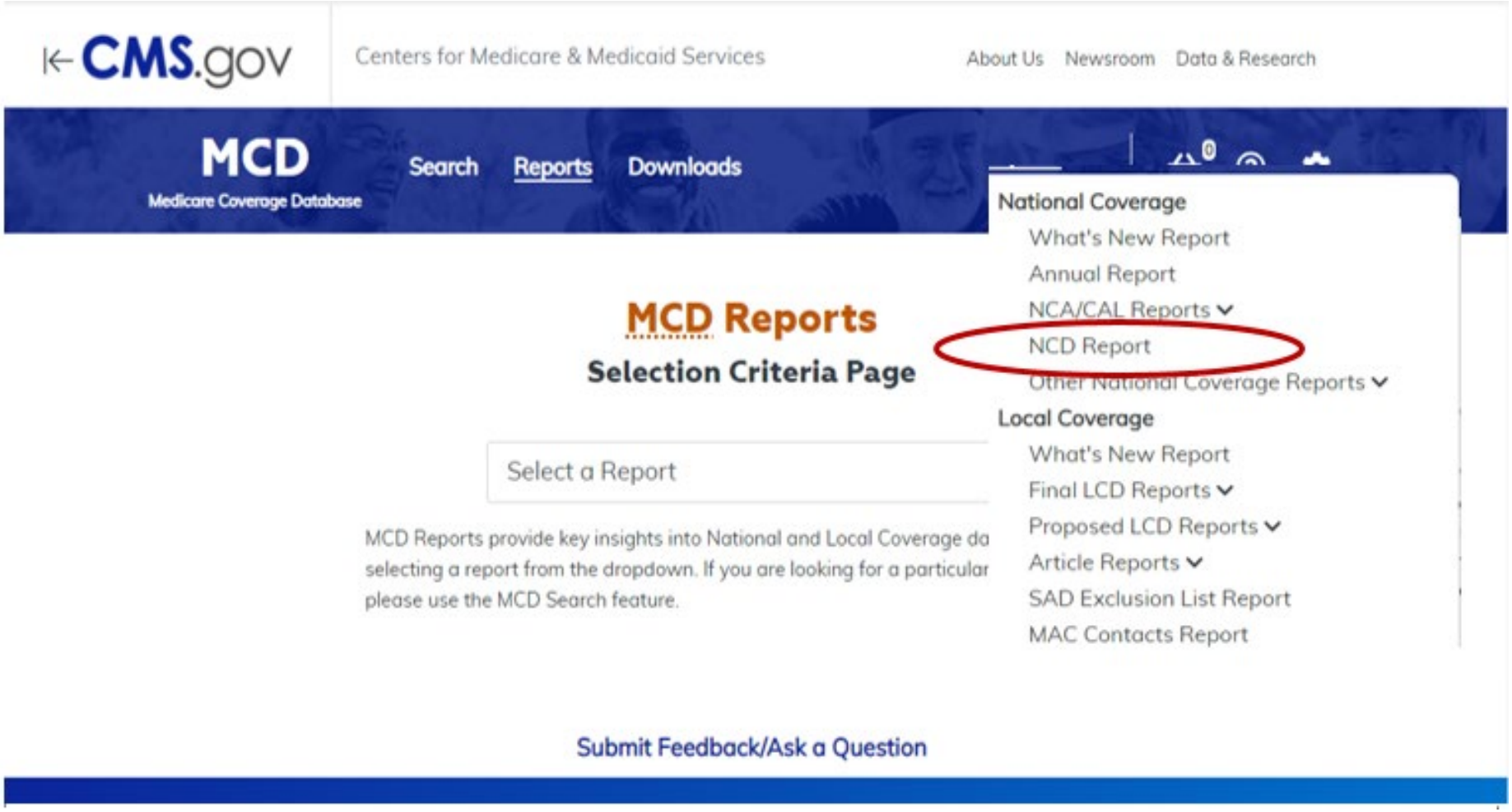
Medicare Coverage Database



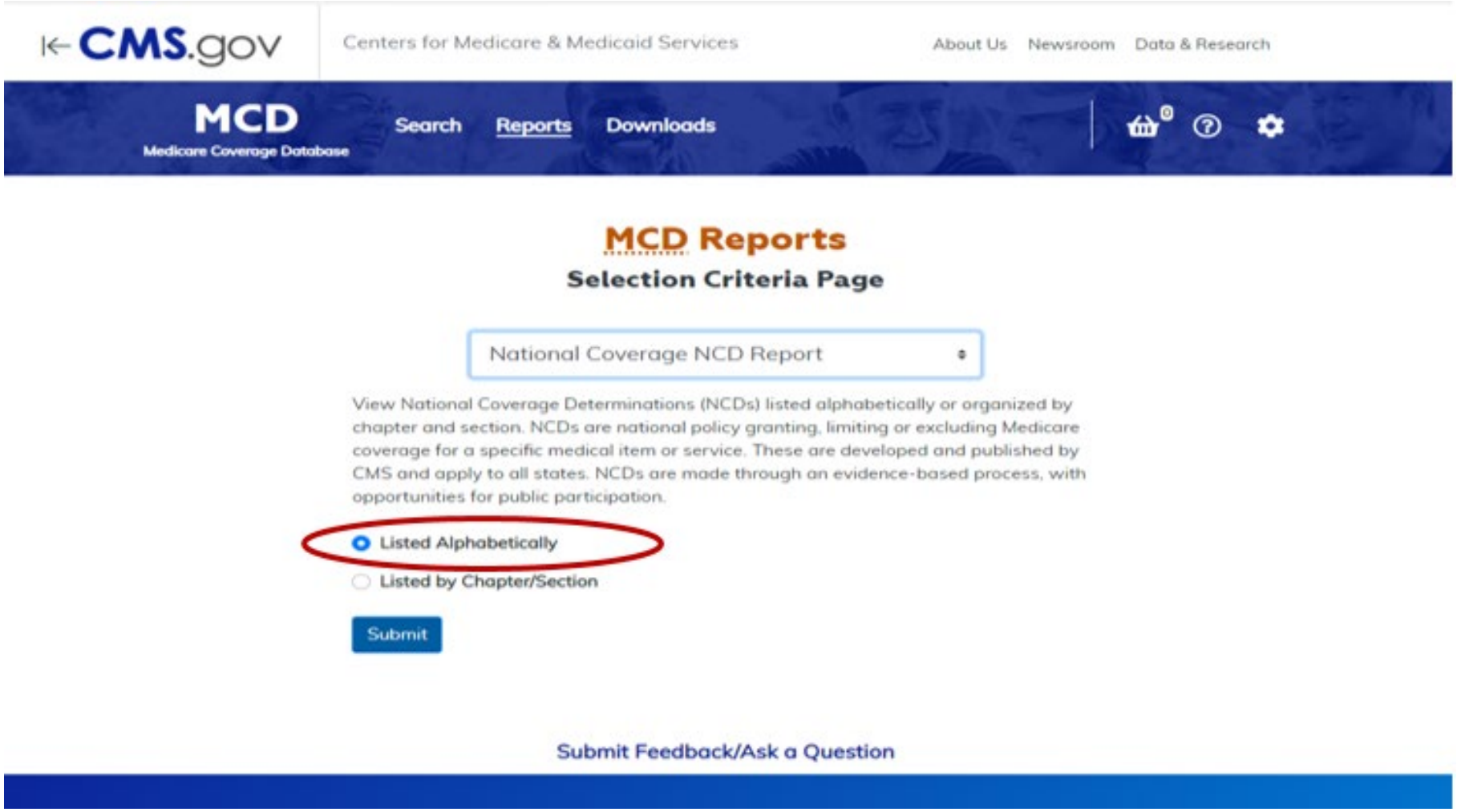
Medicare Coverage Database



Medicare Coverage Database



Medicare Coverage Database



Medicare Coverage Database

Resources

- Medicare Coverage – General Information Labs NCDs – ICD-10

Screening Tests

Medicare Preventive Services

Medicare Preventive Services

Diabetes Screening

Print

HCPCS & CPT Codes

82947 — Glucose; quantitative, blood (except reagent strip)

82950 — Glucose; post glucose dose (includes glucose)

82951 — Glucose; tolerance test (GTT), 3 specimens (includes glucose)

What's Changed?

- No changes from the last quarter

ICD-10 Codes

- Z13.1

Note: Additional ICD-10 codes may apply. Find individual Change Requests (CRs) and specific ICD-10-CM service codes that we cover on the CMS ICD-10 webpage. Find your MAC's website for more information.

Medicare Covers

- Patients with Medicare Part B with certain diabetes risk factors or diagnosed with pre-diabetes

Note: Patients previously diagnosed with diabetes aren't eligible for this benefit.

Frequency

- 1 screening every 6 months for patients diagnosed with pre-diabetes
- 1 screening every 12 months if previously tested but not diagnosed with pre-diabetes or if never tested

Note: See FAQ on how to check eligibility

Medicare Preventive Services

Patient Pays

- No copayment, coinsurance, or deductible

Other Notes

- Append modifier –TS (Follow-up service) when patients meet the pre-diabetes definition.
- We pay ordering providers' and Durable Medical Equipment (DME) suppliers' DME claims when they're actively enrolled in Medicare on the service date or, in the case of the provider, has a valid opt-out affidavit on file. If you don't participate in Medicare, tell your patients before you order DME.

Feedback

FAQs

How do I determine the last date a patient got a preventive service so I know if they're eligible to get the next service and it won't deny due to frequency edits?

Find out how to check for eligibility. You may access eligibility information through the CMS HIPAA Eligibility Transaction System (HETS) either directly or through your:

- Eligibility services vendor
- Medicare Administrative Contractor (MAC) provider call center Interactive Voice Response (IVR) unit
- MAC provider web portal

Contact your eligibility service vendor or find your MAC's website.

When can CMS add new Medicare preventive services?

We may add preventive services coverage through the National Coverage Determination (NCD) process if the service is:

- Reasonable and necessary for prevention or early detection of illness or disability
- United States Preventive Services Task Force (USPSTF) recommended with grade A or B
- Appropriate for individuals entitled to Part A benefits or enrolled under Medicare Part B

We may also add preventive services through statutory and regulatory authority.

The USPSTF Published Recommendations webpage has more preventive services information.

Laboratory Modifiers

CLIA Waived Test

- Modifier QW
  - Not all CLIA-waived tests require modifier QW
- Tests granted waived status under CLIA
  - MLN Matters® *MM12581 Revised: New Waived Tests*

Reference Outside Laboratory

- Modifier 90
  - Diagnostic tests subject to anti-markup price limitations
  - Item 32 or the electronic equivalent must reflect the place where the test was performed
- Centers for Medicare & Medicaid Services Internet-Only-Manual, Publication 100-04, *Medicare Claims Processing Manual,* Chapter 16 – Laboratory Services, Section 40.1.1.1

Repeat Clinical Diagnostic Laboratory Services

- Modifier 91
  - Repeated lab procedures
  - Same day
  - Medically necessary
- Do not use modifier 91 to report
  - Laboratory errors
  - Quality control
  - Confirmation of results

Tests Ordered Individually

- Modifier QP
  - Documentation on file showing laboratory test(s) ordered individually or ordered as CPT-recognized panel other than automated profile codes
  - Physician may order mix of panels and individual tests, but physician should review what tests are in each panel and not order individual tests that duplicate tests in panel
  - QP modifier with the single ordering of tests or when a single code is available for groupings of tests

Laboratory Round Trip

- Modifier LR
  - Laboratories should submit HCPCS modifier LR as informational purposes only to indicate "Round Trip"
  - When using HCPCs code P9604; travel allowance, prorated trip charge
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 16 – Laboratory Services

Distinct Procedural Services

- Modifiers 59, XE, XP, XS, XU should be used to indicate repeat or distinct laboratory services when reported by same individual physician or other QHCP
- Modifier 59 is used to report procedures that are distinct or independent
  - Performing same procedure (that uses the same procedure code) for testing of different specimen or different strain

Place of Service

POS Laboratory Specimen Collections

- POS designation identifies location where laboratory specimen was collected
  - Independent Laboratory or Reference Laboratory
    - POS 81
  - Office/clinic
    - POS 11
  - Facility setting
    - POS 21 or 22

Specimen Collection

Specimen Collection

- Date specimen was collected
- Specimens collected over span of dates, use date collection ended
- Exceptions
  - Date test performed on stored specimens
  - Date for chemotherapy sensitivity test performed on live tissue
  - Date for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests

Stored Specimen

- Stored less than or equal to 30 calendar days from collection, date of test must be date test was performed only if
  - Test is ordered by physician at least 14 days following date of patient's discharge from hospital
  - Specimen was collected while patient was undergoing hospital surgical procedure
  - It was medically inappropriate to have collected sample other than during hospital procedure for which patient was admitted

Thank You!

- Follow-up email
  - Attendees will be provided a Medicare University Course Code
- Questions?

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