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Medicare Part B Drugs and Biologicals

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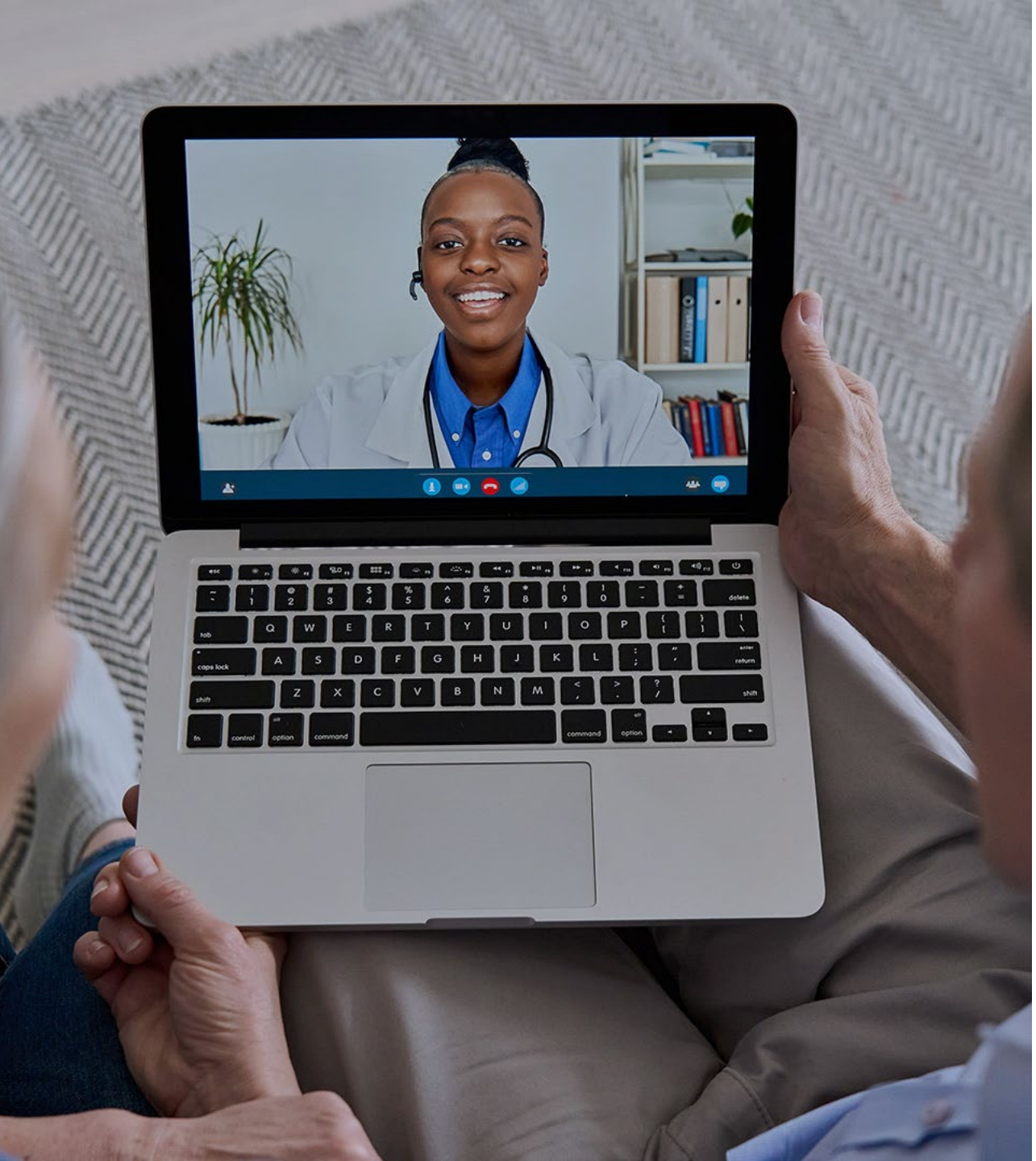

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Objective

During this webinar, we'll focus on coverage and billing information for drugs and biologicals that are billed to Medicare Part B.

Today's Presenters

Jennifer DeStefano

Provider Outreach and Education Consultant

Jennifer Lee

Provider Outreach and Education Consultant

Agenda

- Medicare Part B Coverage
- Drug Pricing and Reimbursement
- Vaccinations and Administration
- Clinical Trials
- Not Otherwise Classified and Compound Drugs
- Self-Administered Drugs
- Free of Charge Drugs and Biologicals
- Reporting Waste for Drugs and Biologicals
- General Billing Guidelines for Drugs and Biologicals

Medicare Part B Drug Coverage

Medicare Part B Coverage – Drugs and Biologicals

- Drugs and biologicals are covered only if all the following requirements are met
  - Meet definition of drugs and biologicals
  - Meet all general requirements for covered items as incident to physician's service
  - Reasonable and necessary for diagnosis or treatment of illness or injury for which are administered
  - Type that are not usually self-administered
  - Not excluded as noncovered immunizations
  - Not been determined by FDA to be less than effective
- Drugs and Biologicals

Drug Pricing and Reimbursement

Average Sales Price

- CMS prices drugs based on average sales price
  - ASP files are updated by CMS quarterly
  - Medicare Part B Drug Average Sales Price
- **Note:** NOC and compound drugs not listed on ASP files are priced by MAC

Wholesale Acquisition Cost/Invoice Pricing

- Payment allowance limits for drugs and biologicals that are not included in ASP or NOC files are based on a percentage of the published WAC or invoice pricing
- CMS IOM, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology
- NGS can decide the number of invoices needed to determine reimbursement amounts for drugs priced by invoice
  - Separate invoice for each claim
    - - OR -
  - Establish payment amounts based on a smaller number of invoices that are representative of providers' costs

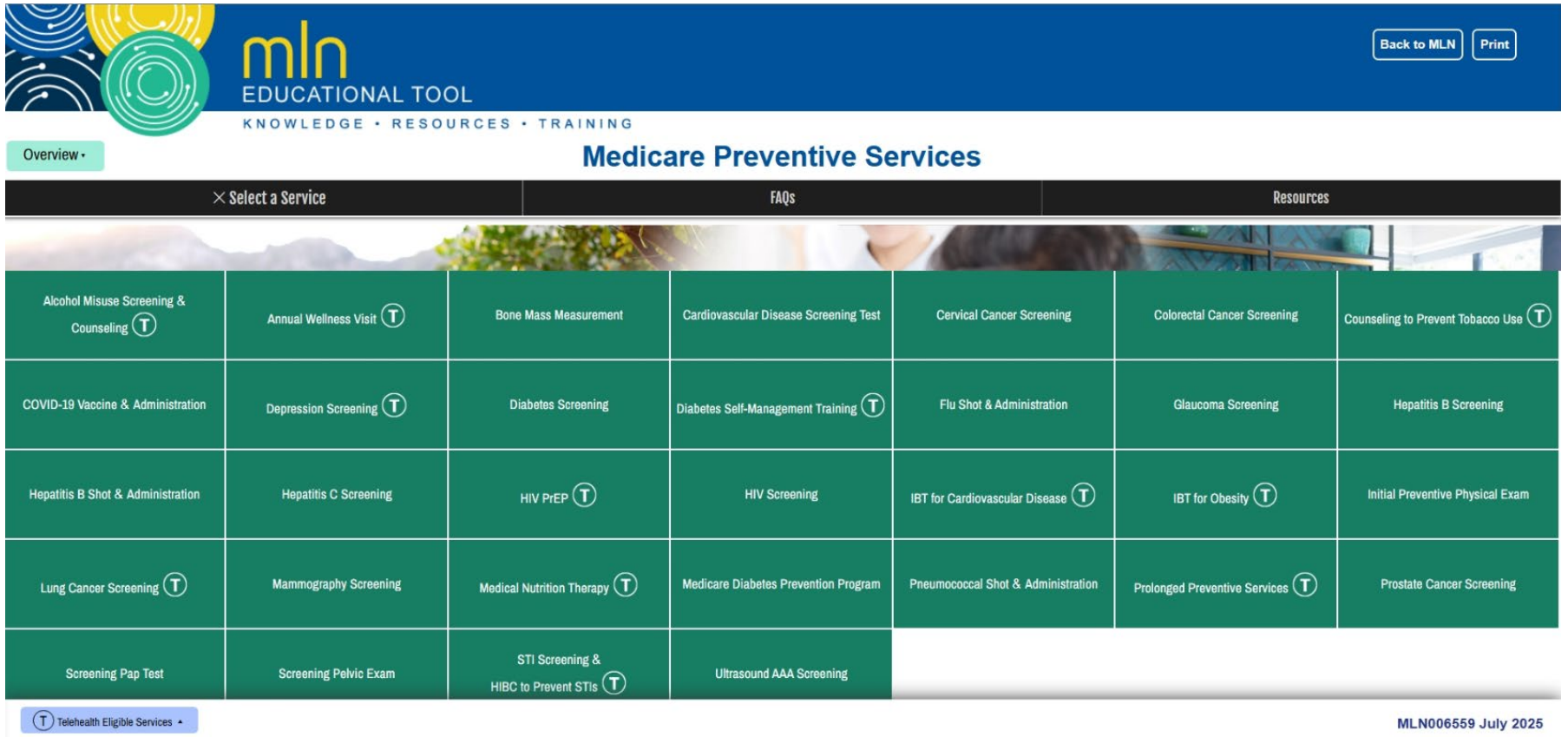
Mandatory Assignment on Claims

- Payment for drugs and biologicals covered under Medicare Part B is made on an assignment basis
  - All claims processed as assigned
- Patients can only be billed for applicable Medicare Part B deductible and coinsurance amounts
- CMS IOM, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 50

Vaccinations and Administration

Vaccinations and Administration

- MLN® Educational Tool: *Medicare Preventive Services*



Clinical Trials

Clinical Trials

- A clinical trial is an interventional study where treatment is evaluated by qualified researchers who have developed an approved protocol
  - Interventions include both diagnostic and therapeutic services
    - The administration of drugs included in a clinical trial may be covered by Medicare Part B
- Billing Reminder
  - The CT/IDE number is required on the claim
- Clinical Trial Services and Modifiers Q0 and Q1

Reporting Clinical Trial

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
19	2300 REF02 & qualifier REF01 = P4	Key the Clinical Trial Number, preceded by “CT” Example: CT XXXXXXXX
19	2400, SV101-7	When billing an NOC drug code in 24D- must add drug name and dose. When a blinded trial – “drug provided in a clinical trial blinded study,” or “Drug XYZ provided in a clinical trial blinded study”
23	2300, REF02 & qualifier REF01=LX	IDE Number
24D (line 1)	2400, SV101-2	HCPCS code for clinical trial drug
24D (line 2)	2400, SV101-2	Administration code
24 D (lines 1 and 2)	2400, SV101-3	Q0 modifier - drug code Q1 modifier - administration code
28 (line 1)	2300, CLM01	Total charge for drug code = $0.01 (one penny)
28 (line 2)	2300, CLM01	Total charge for administration code

Not Otherwise Classified and Compound Drugs

Not Otherwise Classified

- Use appropriate NOC code
  - J3490 – Unclassified drug
  - J3590 – Unclassified biological
  - J9999 – Not otherwise classified, anti-neoplastic drug
- Bill one service unit
  - 2400/SV1-04 data element or in line item 24G of CMS-1500 form
- Details required in the notes section of the claim
  - Name of the drug
  - Dose administered (mg, cc, etc.)
  - Route of administration (IV, IM, SC, PO, etc.)
  - Invoice price (for new drugs if WAC is unavailable, or for compounded drugs)

Compound Drugs – J7999

- Compound drugs is the process of combining or mixing two or more individual drugs to create a medication that is tailored to the needs of a specific patient
    - Examples – patient has allergies, cannot swallow a pill, cannot have dyes in their medications, etc.
  - Bill HCPCS code J7999 on one line item, representing the drugs included in the compound
    - Do not bill each drug on a separate line item
- Details required in the notes section of the claim
    - Each drug name
    - Each drug dosage
    - Route of administration
    - Invoice price

Self-Administered Drugs

Self-Administered Drugs

- A drug that is self-administered by more than 50% of the Medicare beneficiary population is excluded from Medicare Part B coverage
- CMS requires MACs to determine when a drug is excluded under SAD using instruction from
  - CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.2: Determining Self-Administration of Drug or Biological

Self-Administered Drugs - Exclusions

- NGS list of Medicare excluded drugs and biologicals
  - Self-Administered Drug Exclusion List: Medical Policy Article (A53021)
- Criteria used by NGS to determine SAD
  - Process for Determining Self-Administered Drug Exclusions – Medical Policy Article (A53020)

Reporting SAD

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
24D (line 1)	2400, SV101-2	Drug HCPCS (established code or NOC code)
24D (line 1)	2400, SV101-2	GY modifier
24D (line 2)	2400, SV101-2	Drug administration code
24D (line 2)	2400, SV101-2	GY modifier
28 (line 1)	2300, CLM02	Total charge drug code = $0.01
28 (line 2)	2300, CLM02	Total charge for administration code

Free of Charge Drugs and Biologicals

Free of Charge Drugs

- A drug/biological must represent an expense to the provider to be considered as a separate payment under Medicare Part B
- There is no expense to the provider when
  - The provider received the drug free of charge
  - The patient purchased/supplied the drug on their own
- The provider is entitled to reimbursement for administration of the medication
  - This requires specific billing requirements
    - The drugs HCPCS code total charge must be $0.01 (one penny)
    - The administration code will be its actual charge to ensure full reimbursement

Reporting Free of Charge

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
19	2300 or 2400, NTE02	Narrative – “Patient supplied” or “Provided Free of Charge”
24D (line 1)	2400, SV101-2	Covered drug HCPCS code: established or NOC drug code
24D (line 2)	2400, SV101-2	Drug administration code
28 (line 1)	2300, CLM02	Total charge = $0.01
28 (line 2)	2300, CLM02	Total charge for administration code

Reporting Waste for Drugs and Biologicals

Drug Waste of Single Dose Container

Medicare Part B may cover the unused portion of a drug/biological that is packaged for single use

- Example
  - A single use container is labeled 100 units; patient received 95 units leaving five units as waste
    - 95 units is billed on one line
    - Five units is billed on a separate line using the JW modifier to identify as waste/discard

Reporting JW Modifier

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
19	2300 or 2400, NTE02 May also use 2400, SV101-7	NDC, invoice cost, dosage
24D (line 1)	2400, SV101-2	Drug HCPCS code
24D (line 2)	2400, SV101-2	The same drug HCPCS code
24 D (line 2)	2400, SV101-3	JW Modifier
24D (line 3)	2400, SV101-2	Drug administration code
24G	2300, CLM01	Units of service are calculated according to the applicable HCPCS code based on dosage

Zero Drug Waste of Single Dose Container

- Medicare Part B providers are required to report modifier JZ when there is zero waste from a single-dose container
  - Claim will reject when JZ modifier is not present, and the drug is designated as a single-dose container
- Example
  - A single use vial is labeled as 100 units; patient received all 100 units leaving zero waste
    - 100 units billed with appropriate HCPCS code
    - JZ modifier is appended to this HCPCS code to indicate no waste

Reporting JZ Modifier

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
19	2300 or 2400, NTE02 May also use 2400, SV101-7	NDC, invoice cost, dosage
24D (line 1)	2400, SV101-2	Drug HCPCS code
24D (line 1)	2400, SV101-3	JZ Modifier
24 D (line 2)	2400, SV101-3	Drug administration code
24G	2300, SV104	Units of service are calculated according to the applicable HCPCS code based on dosage

General Billing Guidelines for Drugs and Biologicals

National Drug Code (NDC)

- Billing Requirements
- NDC is always required on the claim
  - Claim Notes
    - 2400; NTE02 or SV101-7
      - Most used
  - Drug Identification
    - 2410; LIN03
- Multiple NDCs for same drug
  - Bill on separate lines
  - Append modifier 76

Units of Service

For Medicare Part B billing, dosage amounts for each drug or biological are specified in their descriptions. Enter the units of service on the claim in multiples as indicated in the HCPCS narrative, using the description to determine the correct units

- Example
  - Q5147 – Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg
    - Per eye dose = 2mg
    - May bill 4 units if both eyes treated
    - LCD L33394, A52451
      - Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Aflibercept HD, Brolucizumab-dbll, Faricimab-svoa, and PAVBLU™aflibercept-ayyh, AHZANTIVE®aflibercept-abzv. and ENZEEVU™aflibercept-mrbb

Modifier 76 for Drugs and Biologicals

- **IF** the same drug code must be billed on separate lines for the same DOS, and the provider expects payment for both
- **THEN** modifier 76 must be added to the second drug code
  - Line 2 will deny duplicate if modifier 76 is not reported
- Examples for using modifier 76
  - High dollar charges
  - High number of units
  - Different NDC on vials of same drug HCPCS code
- Medicare Part B Electronic Claims that Exceed the Threshold for Charges and Units of Service
  - Maximum units of service per claim is 9,999
  - Maximum billed amount per claim is $99,999.99

Reporting Modifier 76

1500 Claim Field	ANSI 837 v5010 Loop and Segment	Information Required
24D (line 1)	2400, SV101-2	Drug HCPCS code
24D (line 2)	2400, SV101-2	Same drug HCPCS code
24D (line 2)	2400, SV101-3	Modifier 76
24D (line 3)	2400, SV101-2	Drug administration code

Claim Notes Section – 837P

- 837P – standard format for electronically submitting claims
- Notes are added to 837P, and claim/nurse reviewers ensure data meets claim requirements to permit claim payment
  - Claim is rejected if missing/incomplete/invalid notes
- Loop 2400; Segment NTE02 or SV101-7
  - Equivalent of Item 19, CMS 1500
    - Medicare Part B CMS-1500 Crosswalk for 5010 Electronic Claims

Claim Notes - Examples

Correct	Incorrect
• *"Protonix 40 mg IV"*	• *"Protonix injection"*
• *"Cabenuva (cabotegravir 600 mg; rilpivirine 900mg)"*	• *"Cabenuva buy and bill"*

Resources

Resources

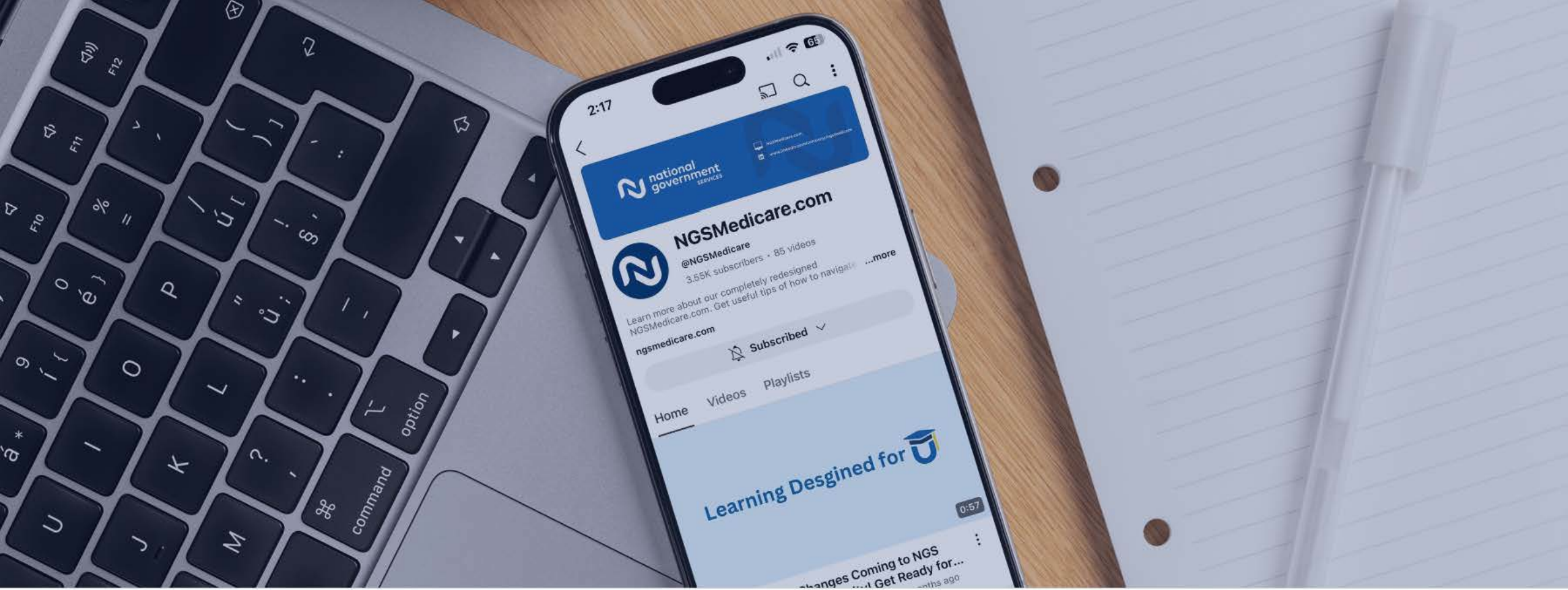
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17
  - Sections
    - 10 Payment Rules for Drugs and Biologicals
    - 20.1.3 Exceptions to Average Sales Price (ASP) Payment Methodology
    - 20.2 Single Drug Pricer (SDP)
    - 40 Discarded Drugs and Biologicals
    - 50 Assignment Required for Drugs and Biologicals
    - 70 Claims Processing Requirements – General
    - 80 Claim Processing for Special Drug Categories
- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15
  - Sections
    - 50–50.4.8 Drugs and Biologicals
    - 50.5–50.6 Self-Administered Drugs and Biologicals

Resources

- Drugs and Biologicals
- Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)
- Drug Coverage under Different Parts of Medicare
- JW Modifier and JZ Modifier FAQs
- Drug and Biological FAQs
- Medicare Part B CMS-1500 Crosswalk for 5010 Electronic Claims

Questions?

Thank you!



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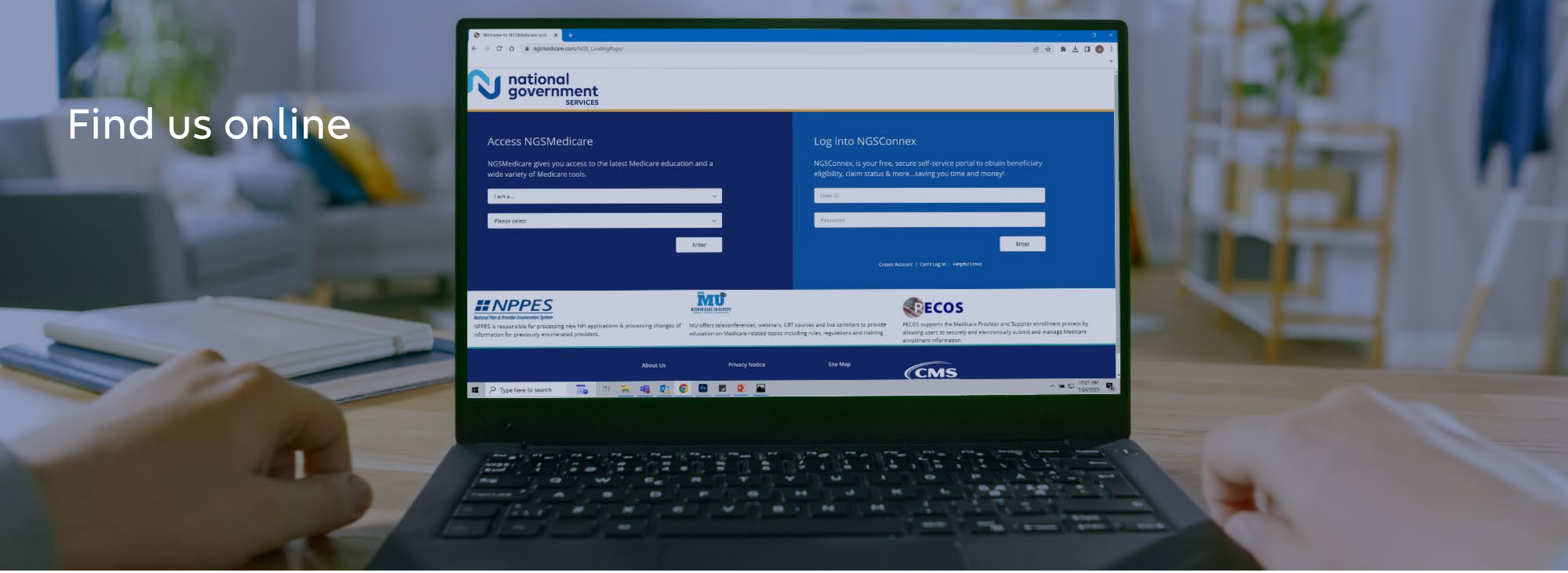

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