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Medicare Part B Drugs and Biologicals

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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

Michele Poulos

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
- Claim Notes and NDC
- Units of Service
- Discarded Drugs and Biologicals
- Free of Charge Drugs and Biologicals
- Self-Administered Drugs
- Modifier 76 for Drug and Biological Claims
- Claim Corrections
- Resources

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

Medicare Part B Coverage

- Below are examples of covered Medicare Part B drugs and biologicals, not be inclusive, along with a resource for coverage information
  - Antigens
  - Blood clotting factors
  - Drugs used with DME
  - Erythropoiesis Stimulating Agent
  - Injectable and infused drugs
  - Injectable osteoporosis drugs
  - Oral antinausea drugs
  - Intravenous Immune Globulin
  - Oral ESRD drugs
  - Oral cancer drugs
  - Transplant drugs
  - IVIG and Rituximab

Medicare Part B Coverage

- Skin Substitutes
  - Total manufacturer's invoice cost
  - JW and JZ modifiers apply
  - High Dollar Claims
    - Append modifier 76, or comment claim one of four, two of four, etc.
  - Ensure units are a product of nine
  - Include wound DX
- LCD – Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound (L39139)

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
- 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
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 - must be appended to both admin and drug 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
- These details must be included 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
  - Required information in notes section of the claim
    - Each drug name
    - Each drug dosage
    - Route of administration
    - Invoice price

Claim Notes and NDC

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

Note Examples

“pavblu aflibercept-ayyh 2mg-intravitreal NDC55513005601

“300mg of Dupixent was injected subcutaneously

“pavblu pfs buy and bill 2 me”

“Xylocaine”

Posting NDC To Claims

- When billing a drug/biological, regardless of classified or unclassified, the NDC is required on the claim
- Claim Notes
  - 2400; NTE02 or SV101-7
    - Most used
- Drug Identification
  - 2410; LIN03

Units of Service

Units of Service

- Each drug/biological defines dosage amount in its description
  - For Medicare Part B billing purposes, the units of service on the claim for a drug/biological are entered in multiples of the units shown in the HCPCS narrative
  - Use the description to determine the correct units to submit on the claim
- Example
  - J7320 – Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
    - There are 25 mgs per dose; therefore, each dose is 25 units
- Resources
  - Billing and Coding Hyaluronans Intra-articular Injections (A52420)
  - CMS IOM, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 70

Discarded Drugs and Biologicals

Payment for Unused Portion of Single Dose Container – JW Modifier

- Medicare Part B payment may be made for the unused portion of a single dose vial of a drug/biological
  - Medicare Part B will pay for the dose that was administered to the patient as well as the remaining dose that had to be discarded
  - Report JW modifier to be eligible for payment
- 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

Reporting Zero Drug Waste of Single Dose Container – JZ Modifier

- 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

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

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

Modifier 76 for Drugs and Biological Claims

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
- Maximum units of service per claim is 9,999

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 Corrections

Claim Corrections

- Part B providers may submit a Reopening when they need to correct a paid claim or when they need to refund a payment
  - Use NGSConnex –Initiate a Clerical Reopening
    - Providers that do not use NGSConnex submit requests by mail
  - Reopening will correct the claim and issue any additional payment requested, or it will create an overpayment if refunding full payment
  - Medicare timely filing standards apply
- Resources
  - Reopenings for Minor Errors and Omissions
  - Overpayments
  - *NGSConnex Part B User Guide*

Resources

Resources

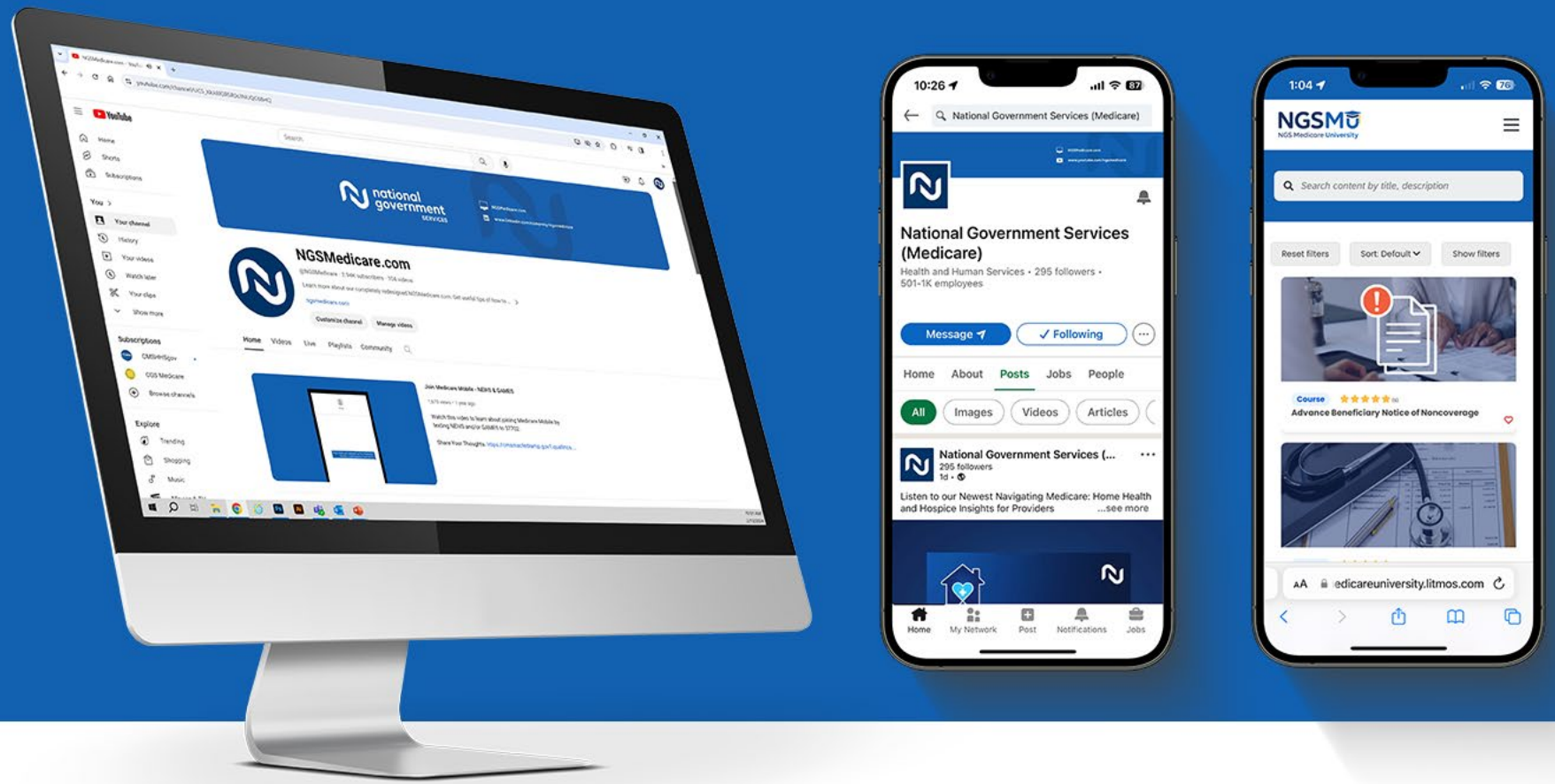
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17
- Sections
  - 10 Payment Rules for Drugs and Biologicals
  - 20.1.3 Exceptions to Average Sales Price (ASP) Payment Methodology
  - 20.2 Single Drug Pricer (SDP)
  - 40 Discarded Drugs and Biologicals
  - 50 Assignment Required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

Resources

- 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
- 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

Questions?

Thank you!



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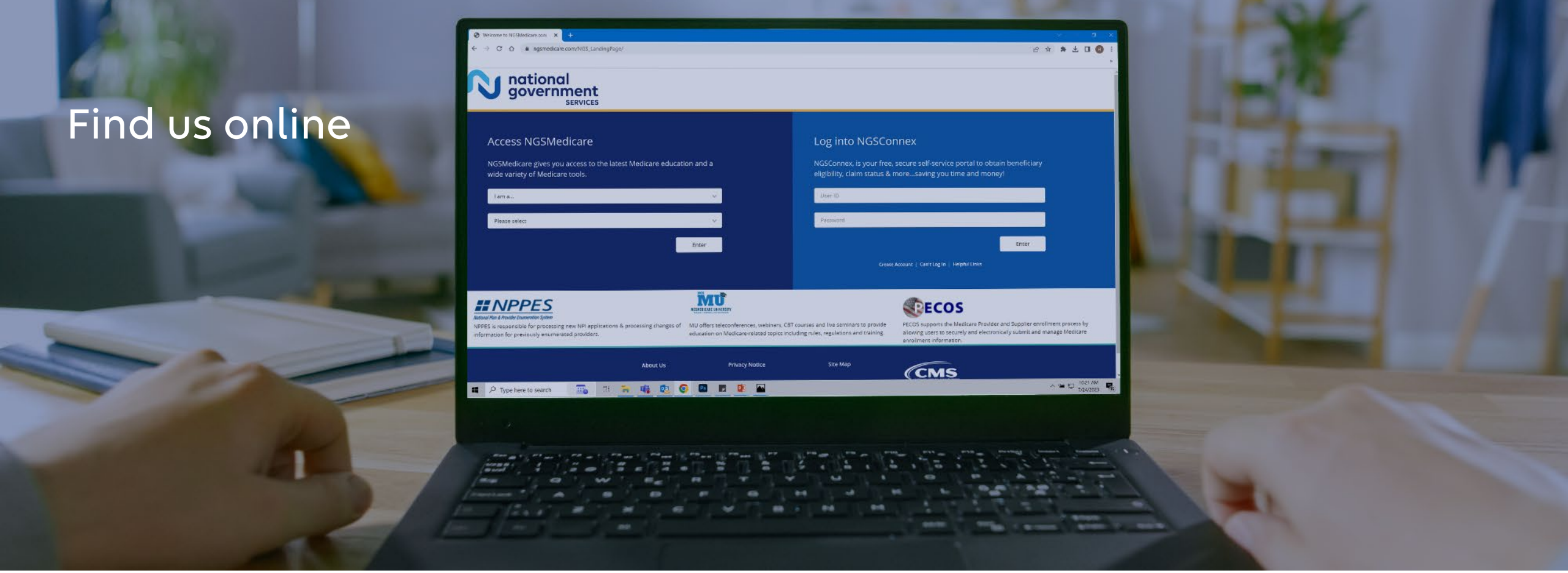

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