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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 covered by Medicare Part B.

# Today's Presenters

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# Agenda


- Medicare Part B Coverage
- Drug Pricing and Reimbursement
- Medicare Part B Vaccines and Administration
- Drug and Biological – Clinical Trial
- Not Otherwise Classified and Compound Drugs
- Units of Service for Drugs and Biologicals
- Discarded Drugs and Biologicals
- Free of Charge Drugs and Biologicals
- Self-Administered Drugs
- References

# 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
- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, Section 50

# 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 Drug Coverage

# 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 published WAC and includes invoice pricing
- NGS has the discretion to determine how many invoices are necessary to determine reimbursement amounts for drugs subject to invoice pricing
  - 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

# Claim Corrections

- Once a claim is paid you must either
  - Submit an Appeal
  - Voluntary Refund and Rebill
    - Timeliness Standards

# Medicare Part B Vaccinations and Administration

# Vaccinations and Administration

- G0008 – Influenza Administration Code
  - Influenza Virus Vaccine and Administration
- G0009 – Pneumococcal Administration Code
  - Pneumococcal Vaccine and Administration
- G0010 – Hepatitis B Administration Code
  - Hepatitis B Virus Vaccine and Administration
- COVID –
  - COVID-19 Vaccines & Monoclonal Antibodies
  - COVID vaccine administration code is dependent upon the vaccine and dosage being given

# Drug and Biological – Clinical Trials

# Drug and Biological – 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"<br>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.
  - These details must be included in the notes section of the claim
    - Each drug name
    - Each drug dosage
    - Route of administration
    - Invoice price

# Claim Notes Section

- CMS 1500 – Paper claim
  - Item 19
- 837P, version 5010
  - Not otherwise classified (NOC) Drug
  - [Medicare Part B CMS-1500 Crosswalk for 5010 Electronic Claims]

# Units of Service for Drugs and Biologicals

# 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 description
- Example
  - Billing and Coding Hyaluronans Intra-articular Injections (A52420)
  - Use drug code description to determine the correct units to submit on the claim
    - "1mg" = total number of milligrams dosed
    - "per dose" = one unit, always
  - J7320 – Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
    - There are 25 mgs per dose; therefore, each dose is 25 units
- More examples
  - CMS IOM, Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 70

# Billing Correct Units J7320 and J7322

- The number of units is calculated by milligrams; each unit being equal to one milligram
- J7320 – Hyaluronan or derivative, GenVisc® 850, for intra-articular injection, one mg
  - There are 25 mgs per dose; therefore each dose is 25 units
  - Proper Billing Units for HCPCS Code J7320
- J7322 – Hyaluronan or derivative, hymovis, for intra-articular injection, one mg
  - There are 24 mgs per dose; therefore each dose is 24 units

# Billing Correct Units for Q2028

- Q2028 - Injection, Sculptra, 0.5 mg
- Sculptra is calculated as 0.5mg and is packaged as a single dose vial (SDV) containing 367.5mg per vial; and cannot be split up for payment
  - Each billing unit = 0.5 mg
  - One vial is 367.5 mg = 735 units
  - Two vials are 735 mg = 1470 units
- Depending on how many vials were administered, total quantity/units billed would be noted as 735 or 1470
- Dermal Injections for Treatment of Facial Lipodystrophy Syndrome

# 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<br>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 – JZ Modifier

- The 2023 Physician Fee Schedule Final Rule included a new requirement for providers to report modifier JZ when zero drug is wasted from a single-dose container, or single-use package
  - This applies to drugs separately payable under Medicare Part B
  - Effective 7/1/2023, providers are required to report JZ modifier
  - Editing began on 10/1/2023
- 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<br>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 an exclusion to 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

- 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 |

# References

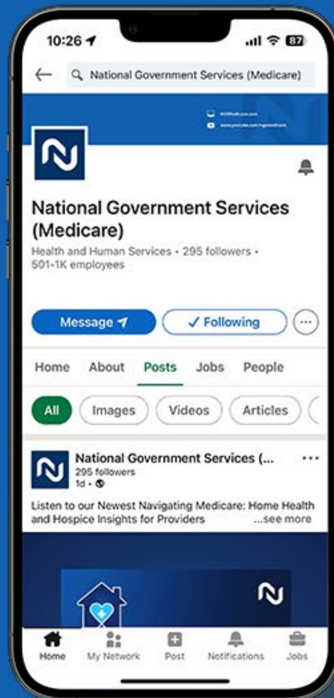
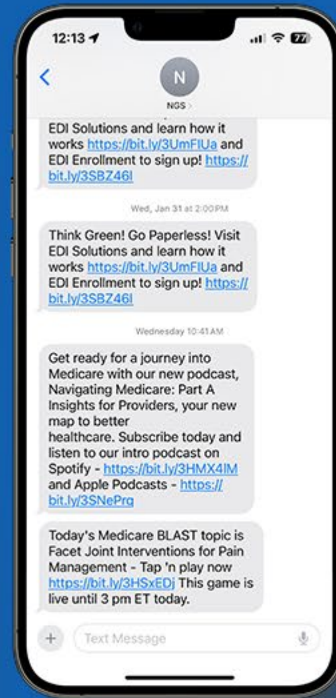
# References

- 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

# References

- 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

Thank you!

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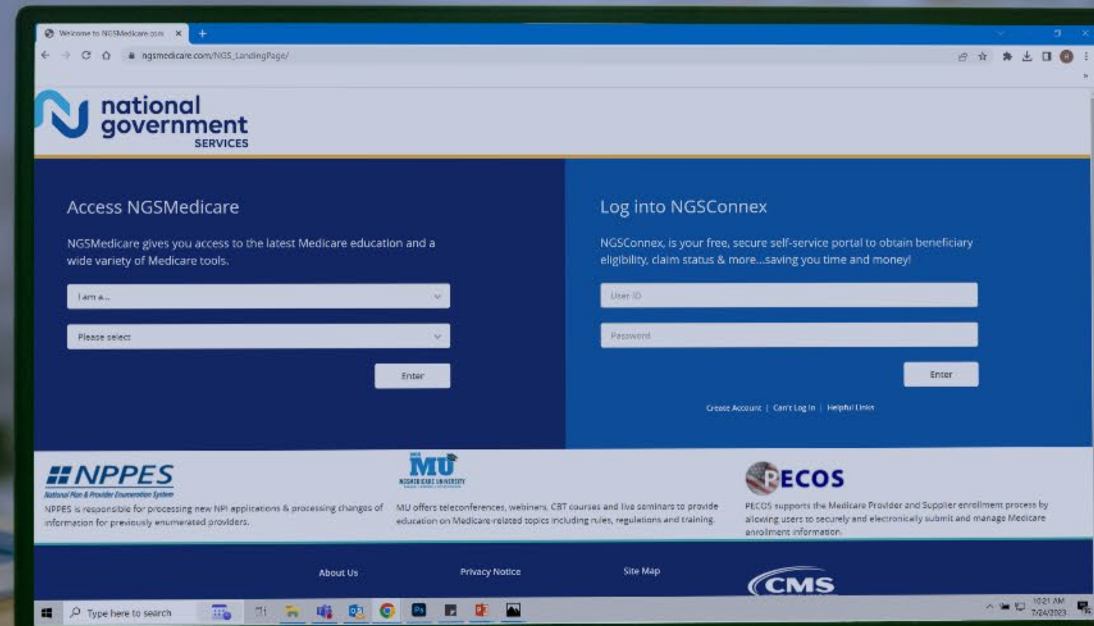

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