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Medicare Part B Drugs and Biologicals

5/23/2023

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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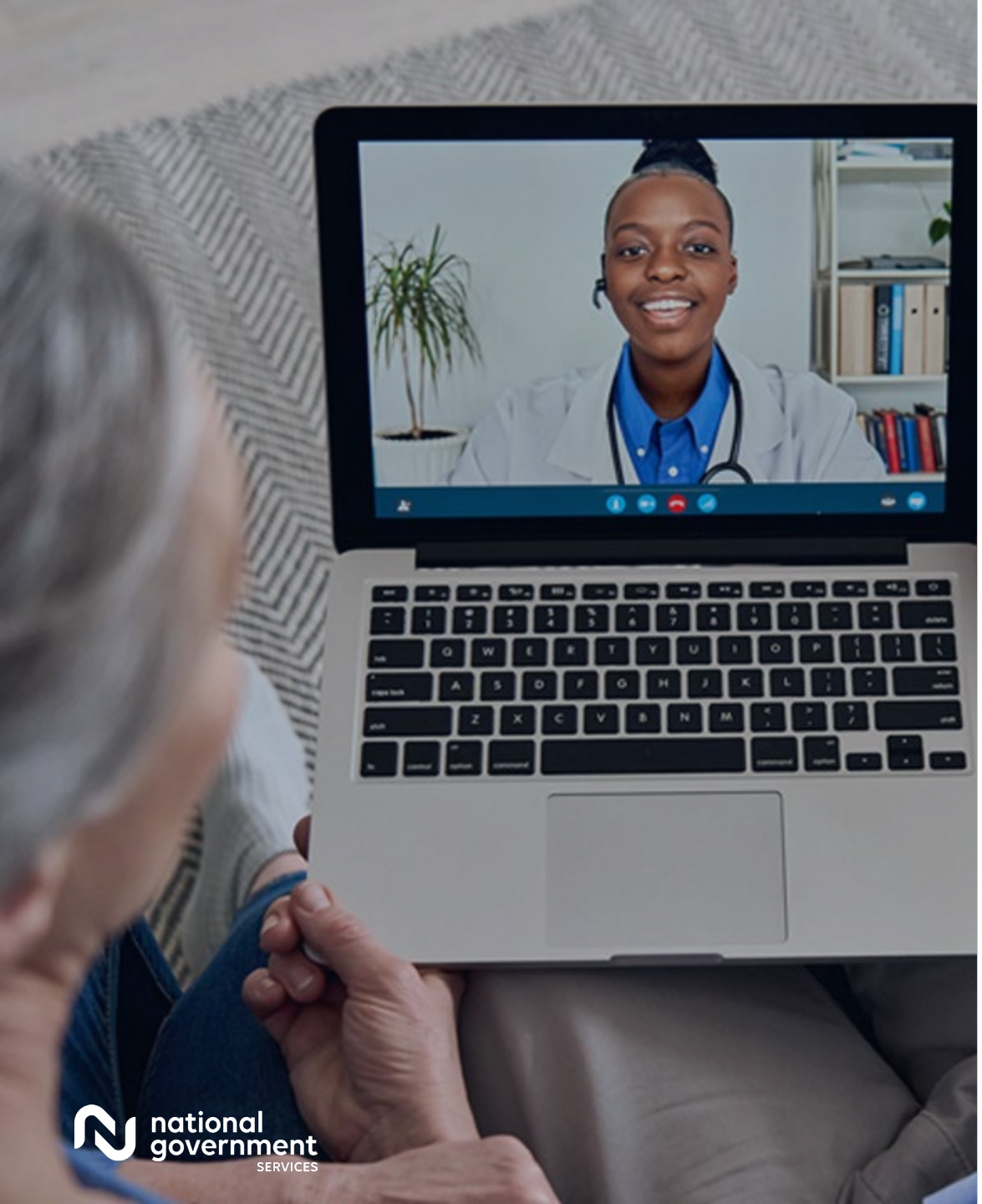

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Objective

To gain a better understanding of the Medicare Part B drug and biological coverage and review the proper billing guidelines.

Today's Presenters

- Provider Outreach and Education Consultants
  - Jennifer Lee
  - Jennifer DeStefano

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Agenda

- Medicare Part B Coverage
- Pricing and Reimbursement
- Vaccinations and Administrations
- Clinical Trial Drugs and Biologicals
- Not Otherwise Classified and Compound Drugs
- Units of Drugs and Biologicals
- Discarded Drugs
- Patient Supplied or Free-of-Charge Drugs
- Self-Administered Drugs

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Medicare Part B Coverage

Medicare Part B Coverage - Drugs and Biologicals

- Drugs and biologicals are covered only if all of 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 (1)

- Antigens
  - CPT codes 95144-95165 are only considered when the antigens are
    - ✓ Prepared by a physician who is a doctor of medicine or osteopathy and has examined the patient, determined a plan of treatment and dosage regimen
    - ✓ Determined by CMS a reasonable supply of antigens, not more than a 12 month supply prepared at any one time
  - The incident-to rule and regulations do not apply
- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.4.4.1

Medicare Part B Coverage (2)

- Blood clotting factors
  - Medicare provides coverage of self-administered blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision
- MLN Matters® *MM10474 Revised: Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients*

Medicare Part B Coverage (3)

- Drugs used with DME
  - Medicare covers drugs infused through DME, such as an infusion pump or drugs given by a nebulizer
- Practitioners: Are You Ordering Nebulizers and Inhalation Medication for Your Patient?

Medicare Part B Coverage [4]

- Erythropoiesis Stimulating Agent (ESA)
  - Not reasonable and necessary for beneficiaries with certain clinical conditions
    - ✓ Damaging effect of the ESA on their underlying disease
    - ✓ The underlying disease increases their risk of adverse effects related to ESA use
  - NCD 110.21: Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

Medicare Part B Coverage (5)

- Enteral and Parenteral Nutrition Therapy
  - Prosthetic benefit for individuals with “permanent” dysfunction of the digestive tract. If medical record, including the judgment or the attending physician, indicates that the impairment will be long and indefinite duration, the test of permanence is met
  - NCD 180.2: Enteral and Parenteral Nutritional Therapy

Medicare Part B Coverage (6)

- Injectable and infused drugs
- Covered when given by a licensed medical provider
  - CPT codes include chemotherapy infusions and injections, therapeutic, prophylactic, diagnostic infusions/injections, and hydration
    - ✓ The start and stop times must be evident in the documentation in order to bill units for hours infused
    - ✓ The use of a doctor's order or pharmacy directive/label to calculate times is not appropriate as correct coding is based on how incidents/services occur; not how services are planned
  - Chemotherapy General Infusion Information

Medicare Part B Coverage [7]

- Injectable osteoporosis drugs
  - LCD L37535 – Vitamin D Assay Testing
- Oral antinausea drugs
  - The drugs must meet both these conditions
    - ✓ Be administered immediately before, at, or within 48 hours after chemotherapy
    - ✓ Be used as a full therapeutic replacement for an intravenous anti-nausea drugs
- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.5.4

Medicare Part B Coverage (8)

- Intravenous Immune Globulin
  - The dose and frequency of administration should be consistent with the FDA approved package insert
    - ✓ When different from the FDA approved package insert, literature to support the specific schedule chosen should be available
  - Claims for procedures performed at unusually frequent intervals/high dosages may be reviewed for medical necessity
    - ✓ If coverage of IVIG is denied, the administration and pre-administration services associated with IVIG will also be denied
- LCD Article A52446: Billing and Coding: Intravenous Immune Globulin (IVIG)

Medicare Part B Coverage (9)

- Oral ESRD drugs
  - Medicare helps pay for some oral ESRD drugs if
    - ✓ The same drug is available in injectable form and
    - ✓ The drug is covered under the Part B ESRD benefit
  - CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 8
- Oral cancer drugs
  - One of the following must apply
    - ✓ The same drug is available in injectable form, or
    - ✓ The drug is a prodrug of the injectable or oral form
  - CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 80.1

Medicare Part B Coverage (10)

- Transplant drugs
  - These drugs are not billable to Medicare Part B
  - Medicare covers prescription drugs used in immunosuppressive therapy under the DME benefit if they meet specific criteria
    - ✓ Unless the transplant occurred prior to Medicare Part A enrollment; may be eligible for coverage under Medicare Part D
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, Section 80.3

Medicare Part B Coverage (11)

- IVIG and Rituximab
  - Coverage for labeled indications continues for NGS jurisdictions
- Indications
  - A medically accepted indication, which is covered by National Government Services is one of the following
    - ✓ An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex®, Elsevier/Gold Standard Clinical Pharmacology and Wolters Kluwer Lexi-Drugs® as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen); or
    - ✓ Articles or Local Coverage Determinations (LCDs) published by National Government Services.
- L33394: Coverage of Drugs and Biologicals, for Label and Off-Label Uses

Medicare Part B Coverage (12)

- What's Changed?
  - Moved coverage for these drugs from articles to new LCDs
  - Only off-label dx are listed in the coding articles
    - ✓ previous articles listed all payable dx, labeled and off-label
- Coding articles attached to the new LCDs
  - Article – Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG) (A59105) (cms.gov)
  - Article – Billing and Coding: Off-label Use of Rituximab and Rituximab Biosimilars (A59101) (cms.gov)

Pricing and Reimbursement

Drug Pricing

- 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

Assignment Required

- 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

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
- CMS IOM, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.4.4.2

COVID-19 Administration

- When COVID-19 vaccine doses are provided by the government without charge, only bill for the vaccine administration
- Do not include the vaccine codes on the claim when the vaccines are free
  - COVID-19 Vaccine and Monoclonal Antibody

General Coding Facts

- The drug code and drug administration code must be submitted on the same claim
  - Exception – COVID-19
- Procedure codes may be subject to NCCI
- Claim(s) submitted without valid ICD-10-CM diagnosis code will be returned to provider as incomplete
- Diagnosis code(s) must best describe the patient's condition for which the service was performed

Clinical Trial Drugs and Biologicals

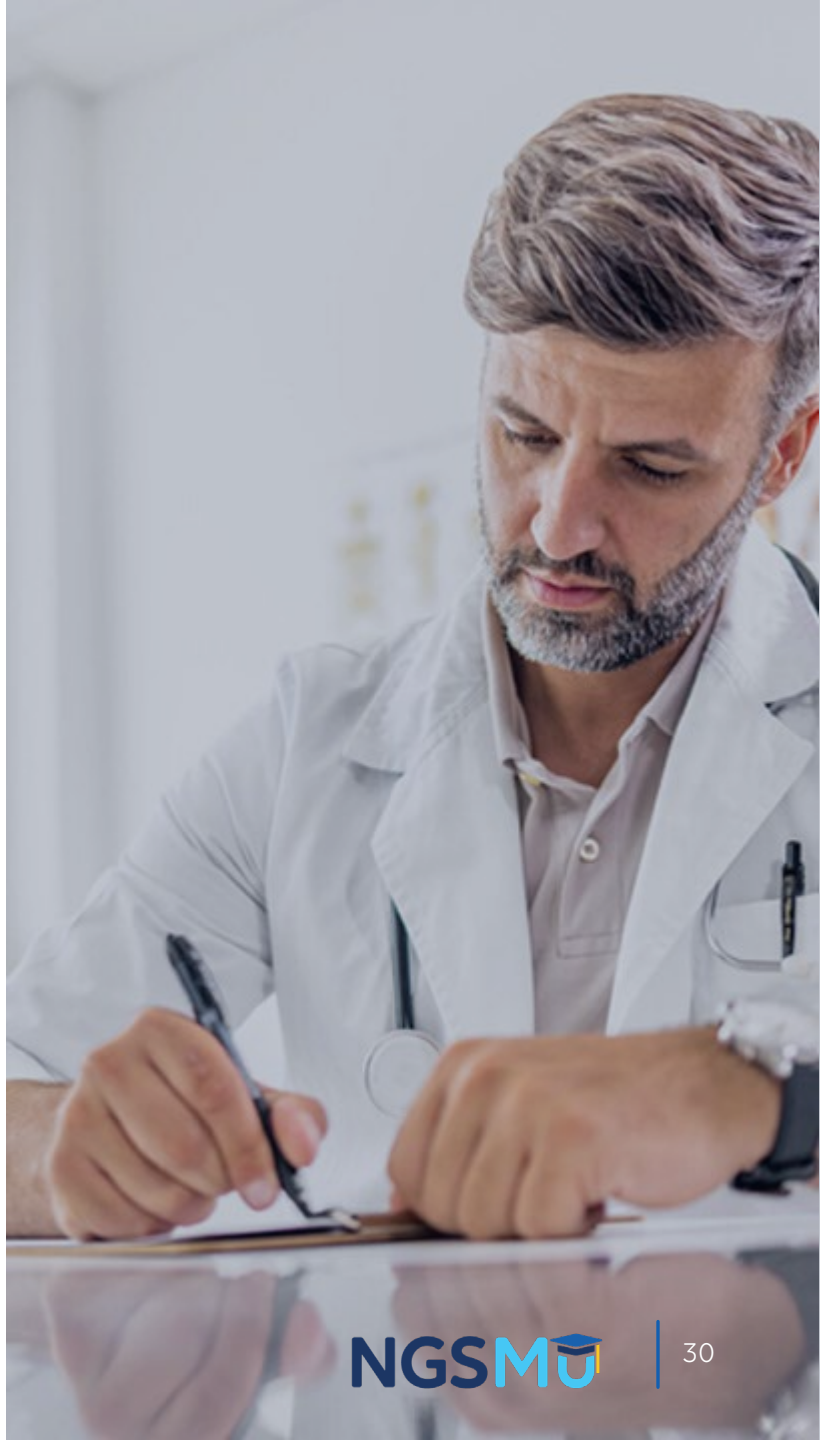
Clinical Trial Drugs and Biologicals

- 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

Billing for Clinical Trial

Drugs/Biologicals

1500 Claim Field	ANSI 837 v5010 Loop & Segment	Information Required
19	2300 REF02 & qualifier REF01=P4	Clinical Trial Number, preceded by "CT" Example: CT XXXXXXXX
23	2300, REF02 & qualifier REF01=LX	IDE Number
24D	2400, SV101-2	HCPCS code for clinical trial drug
24D (line 2)	2400, SV101-2	Administration code
24D (line 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
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
- Must enter information on line Item 19 of CMS-1500 or electronic equivalent
  - 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
  - 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.
  - Include the following in Item 19, or the electronic equivalent
    - ✓ Each drug name
    - ✓ Each drug dosage
    - ✓ Route of administration
    - ✓ Invoice price

Units of Drugs/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
- Billing examples
  - CMS IOM, Publication 100-04, *Medicare Claims Processing Manual,* Chapter 17, Section 70

Unit of Service Example - LCD Article A52420

- LCD Article A52420: Billing and Coding
- Hyaluronans Intra-articular Injections
  - Use drug code description to determine the correct units to submit on the claim
    - ✓ "1mg" = total # of milligrams dosed
    - ✓ "per dose" = 1 unit, always

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, 1 mg
  - There are 25 mgs per dose; therefore each dose is 25 units
  - Proper Billing Units for HCPCS J7320
- J7322 – Hyaluronan or derivative, hymovis, for intra-articular injection, 1 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 the following: 735 or 1470
- Dermal Injections for Treatment of Facial Lipodystrophy Syndrome

Discarded Drugs and Biologicals

Discarded Drugs and Biologicals

- 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 amount of the drug that was administered to the patient as well as the amount of the drug that has been discarded
- JW modifier is used for discarded drugs or biologicals from single use vials or single use packages
  - Append JW to the amount of drug or biological that is discarded, and bill it on a separate line item
  - The discarded drug/biological must be documented in the patient's medical record

Example – JW Modifier

- A single use vial is labeled as 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

Billing Discarded Drugs and Biologicals – JW Modifier

1500 Claim Field	ANSI 837 v5010 Loop & 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
24 D (line 2)	2400, SV101-2	The same drug HCPCS code
24D (line 2)	2400, SV101-3	JW modifier
24D (line 3)	2400, SV101-2	Drug administration code
24G	2400, SV104	Units of service are calculated according to the applicable HCPCS code based on dosage

Modifier JZ

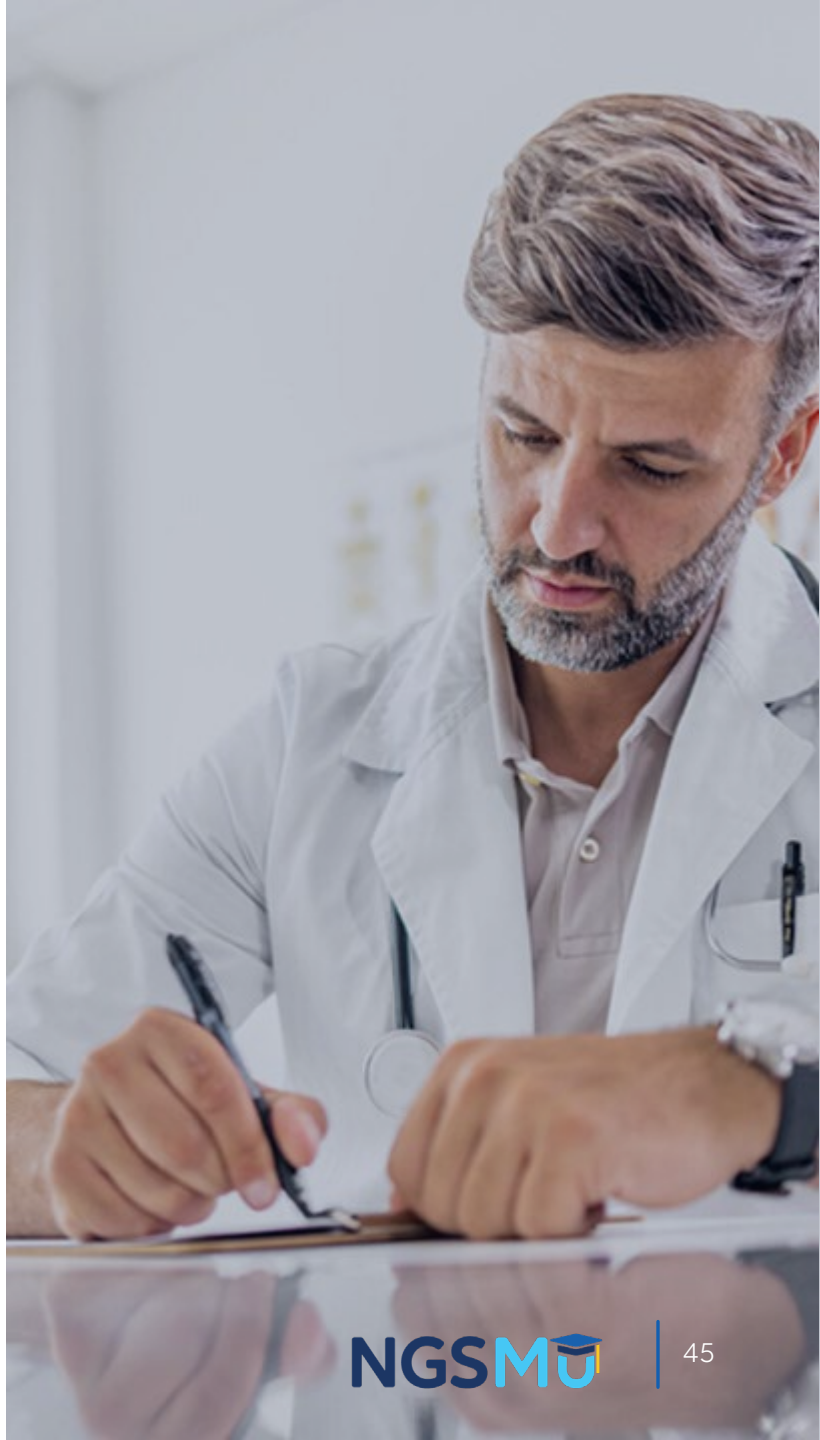
- JZ modifier – Zero drug amount discarded/not administered to any patient
  - Effective for services on and after 1/1/2023
  - Required on claims with receipt dates 7/1/2023 and forward
  - Editing begins 10/1/2023
    - ✓ If JZ not on the claim, it will RTP

Example - JZ Modifier

- A single use vial is labeled as 100 units. Patient received all 100 units; leaving zero waste
  - 100 units billed on line item with appropriate HCPCS code
  - JZ modifier is appended to this HCPCS code to indicate no waste

Billing Discarded Drugs and Biologicals – JZ Modifier

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



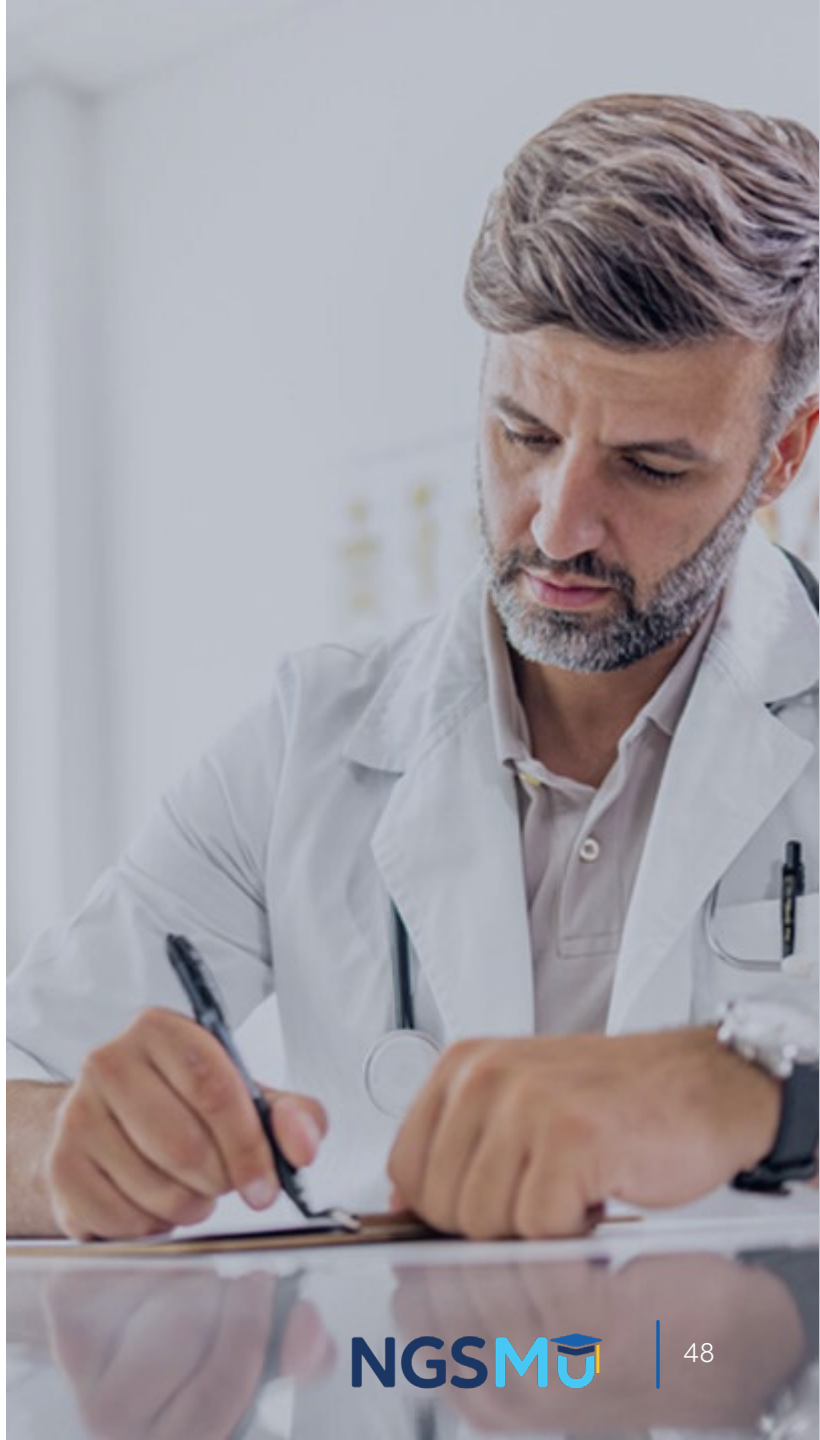
Patient Supplied or Free-of-Charge Drugs

Patient Supplied or Free-of-Charge Drugs

- Charge for drug or biological must be included
  - Physician's bill
  - Cost of drug or biological must represent an expense to physician
- Drug code must be present on same claim
- Include appropriate information CMS-1500 claim form items or electronic equivalents
- Proper Billing for Patient Supplied Drugs

Billing Free-of-Charge Drugs

1500 Claim Form	ANSI 837 v5010 Loop, Segment, Element	Description
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 (SAD)

Self-Administered Drugs

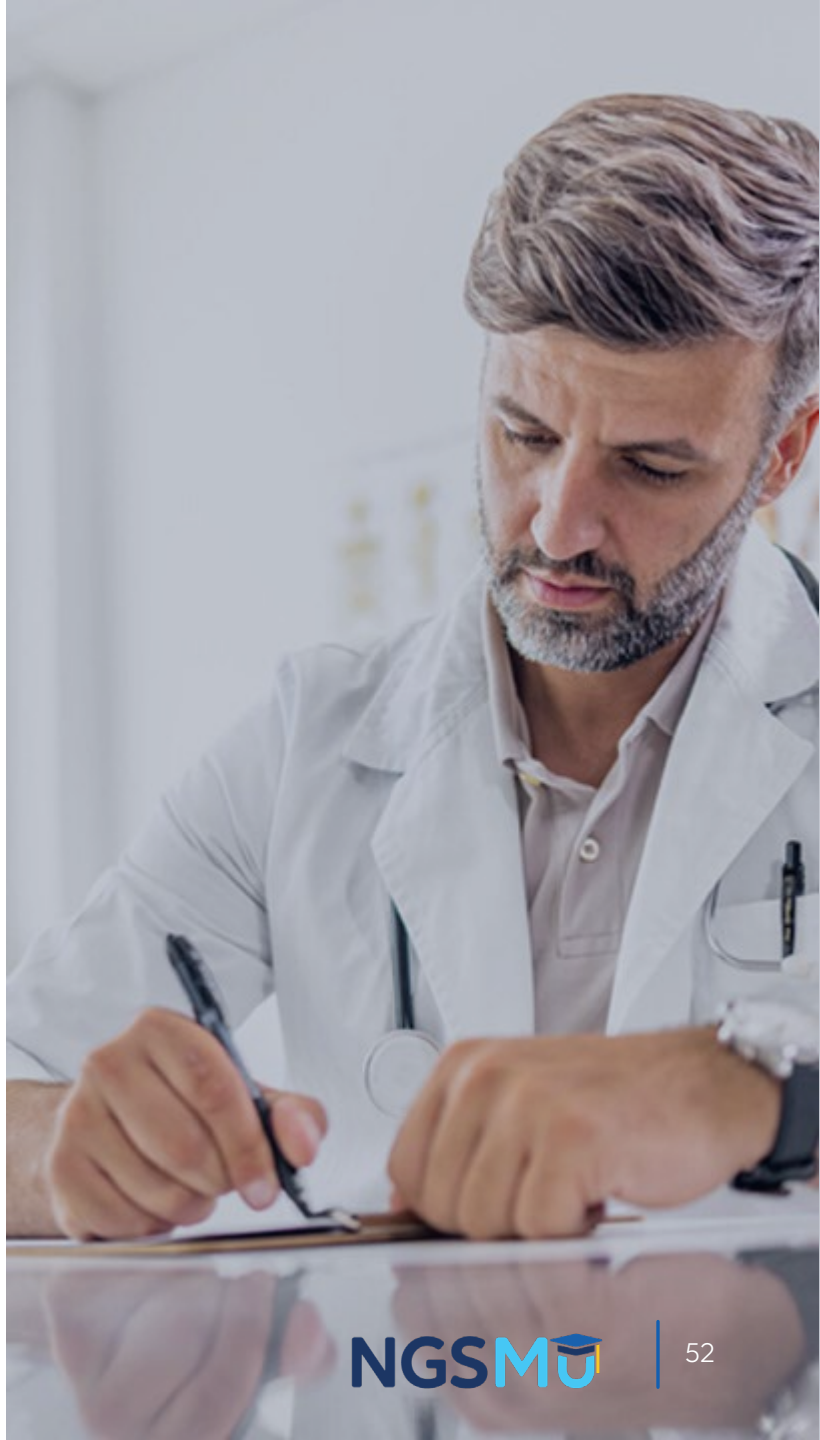
- A drug that is self-administered by more than 50% of the Medicare beneficiary population is an exclusion to coverage
- CMS requires MACs to determine when a drug is excluded under SAD using instruction from
  - CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50.2: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

Billing Excluded SAD

1500 Claim Field	ANSI 837 v5010 – Loop & Segment	Information Required
24D (line 1)	2400, SV101-2	Drug HCPCS (established code or NOC code)
24D (line 1)	2400, SV101-3	GY modifier
24D (line 2)	2400, SV101-2	Administration code
24D (line 2)	2400, SV101-3	GY modifier
28 (line 1)	2300, CLM02	Total charge drug code=$0.01
28 (line 2)	2300, CLM02	Total charge of administration code



References (1)

- 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 (2)

- 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
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17

References (3)

- Drugs and Biologicals – Coverage and Billing
- 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?

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