

# Medicare Part B Drugs and Biologicals

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# Today's Presenters

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# Objective

- To gain an understanding of the current policies and billing guidelines for drugs and biologicals

# Agenda

- Medicare Part B Coverage
- Pricing and Reimbursement
- Vaccinations and Administrations
- Unlisted Drugs – Not Otherwise Classified (NOC)
- Units of Service
- Discarded Drugs

# Medicare Part B Coverage



# Medicare Part B Coverage - Drugs and Biologicals

- Drugs and biologicals are covered only if all 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

- Antigens
- Blood clotting factors
- Compound drugs
- Drugs used with durable medical equipment
- ESAs
- Enteral and parenteral nutrition therapy

# Medicare Part B Coverage

- Injectable and infused drugs
- Injectable osteoporosis drugs
- Intravenous Immune Globulin
- Oral anti-nausea drugs
- Oral ESRD drugs
- Oral cancer drugs
- Transplant drugs (immunosuppressive therapy)

# 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 \(A53020\)](#)

# Pricing and Reimbursement

# Drug Pricing

- CMS prices drugs based on Average Sales Price (ASP)
  - 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 (WAC)/ 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

# Not Otherwise Classified (NOC) - Unlisted

# NOC

- 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)

# Units of Drug/Biological

# 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](#)

# 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 = 0.5mg
  - 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

# 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

# Discarded Drugs and Biologicals

- **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

# Discarded Drugs and Biologicals - Example

- A single use vial that is labeled to contain 100 units of a drug has 95 units administered to patient and five units discarded
- 95 units is billed on one line
- Five units is billed on a separate line using the JW modifier to identify as waste/discard

<b>1500 Claim Field</b>	<b>ANSI 837 v5010 Loop, Segment, Element</b>	<b>Information Required</b>
19	2300 or 2400, NTE, 02	NDC, invoice cost, dosage
24D	2400, SV101, 2	Appropriate drug procedure code
24D	2400, SV101, 3	JW modifier
24G	2400, SV104, NA	Units of service are calculated according to the applicable HCPCS code based on dosage

# 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

<b>1500 Claim Form</b>	<b>ANSI 837 v5010 Loop, Segment, Element</b>	<b>Description</b>
19	2300 or 2400, NTE, 02	Narrative – Patient supplied or Provided Free of Charge
24D	2400, SV1, 01-2	Appropriate drug (HCPCS) code
28	2300, CLM, 02	Billed amount of \$0.01



# 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

- [Drugs and Biologicals- Coverage and Billing](#)
- [Local Coverage Determination \(LCD\): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses \(L33394\)](#)

# Thank You!

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

