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NGS Medicare Virtual Conference

Fall 2021

Drugs and Biologicals

11/10/2021





Today's Presenters

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

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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
- Units of Drugs and Biologicals
- 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 antinausea 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 self-administered drug
 - [Process for Determining Self-Administered Drug Exclusions – Medical Policy Article \(A53020\)](#)

Pricing and Reimbursement

Drug Pricing

- CMS prices drugs based on average sales price
 - Average sales price 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 wholesale acquisition cost 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 co-insurance 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 vaccine codes on claim when 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

Unlisted Drugs – Not Otherwise Classified

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)

Units of 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
- 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, 1mg
 - 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, 1mg
 - There are 24 mgs per dose; therefore each dose is 24 units

Billing Correct Units - Sculptra

- Q2028 - Injection, Sculptra, 0.5mg
- Sculptra is calculated as 0.5mg and is packaged as a single dose vial containing 367.5mg per vial; and cannot be split up for payment
 - Each billing unit = 0.5mg
 - One vial is 367.5mg = 735 units
 - Two vials are 735mg = 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 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 are billed on a separate line using the JW modifier to identify as waste/discard

1500 Claim Field	ANSI 837 V5010 Loop, Segment, Element	Information Required
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

CMS-1500 Claim Form	ANSI 837 V5010 Loop, Segment, Element	Description
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?

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