

BILLING AND CODING GUIDE FOR OUTPATIENT SITES OF CARE

Introduction

Scholar Rock, Inc. has developed this billing and coding guide to help healthcare providers (HCPs) understand general billing and coding considerations for ISEMBYLD™ (apitegromab-mstn) in outpatient sites of care. This guide is provided for informational purposes only and is not intended to be an exhaustive description of all applicable billing and coding requirements that may apply to ISEMBYLD.

Coding, coverage, and reimbursement policies vary by payer and are subject to change, often without notice. Accurate completion of claims—including using appropriate codes and confirming coverage, medical necessity, and payer requirements—is the sole responsibility of the HCP or individual responsible for claims submission. Nothing in this guide should be construed as a promise or guarantee of coverage or reimbursement.

All codes reported and services billed to payers by the HCP or individual responsible for claim submission must be accurate, complete, and fully supported by medical record documentation.

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Indication and Important Safety Information

INDICATION

ISEMBYLD (apitegromab-mstn) is indicated for the treatment of spinal muscular atrophy (SMA) in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Fractures

ISEMBYLD may increase the risk of fractures, including serious fractures. Use with caution in patients with a history of low bone density or multiple fractures. In patients who experience fractures, weigh the risks and benefits of continuing ISEMBYLD.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 20\%$ of patients treated with ISEMBYLD and more frequent than placebo) were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

Based on animal data, ISEMBYLD may cause fetal harm. There are no adequate data on the developmental risk associated with the use of ISEMBYLD in pregnant women. There are no data on the presence of ISEMBYLD in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ISEMBYLD, and any potential adverse effects on the breastfed infant.

Females and Males of Reproductive Potential

Based on animal data, ISEMBYLD may affect male and/or female reproductive function.



Support your patients can count on

Scholar Rock Supports offers coordinated resources and personalized assistance to help patients access treatment—and navigate the treatment journey.

Scholar Rock Supports offers the following for your patients on ISEMBYLD:

- Insurance access and benefits support
- Financial and copay assistance (for eligible patients)
- Infusion day logistical support
- Caregiver support and resources
- Education on what patients can expect with treatment



OUR SCHOLAR ROCK SUPPORTS TEAM IS AVAILABLE
MONDAY THROUGH FRIDAY, 8 AM TO 8 PM ET
CALL: 833-777-5444

Coding Overview

Accurate billing and coding are the sole responsibility of the HCP or individual responsible for claims submission.

The codes listed in this section may potentially be used to report services associated with ISEMBYLD when administered in a physician office, independent infusion center, hospital outpatient department (HOPD), or the home.

Coding for ISEMBYLD in Outpatient Sites of Care

The following codes may be appropriate for reporting ISEMBYLD and its administration.

Healthcare Common Procedure Coding System (HCPCS)

HCPCS codes are used to report drugs and other procedures on outpatient claims. Until ISEMBYLD is assigned a product-specific HCPCS code, it generally would be reported with an unclassified code, such as one of the following:

HCPCS code ¹	Description	Appropriate use
J3490	Unclassified drugs	Check individual payer policies for reporting requirements
J3590	Unclassified biologics	
C9399	Unclassified drugs or biologicals	For Medicare fee-for-service HOPD claims

Key: HCPCS – Healthcare Common Procedure Coding System; HOPD – hospital outpatient department.

Billing With Unclassified HCPCS Codes

Unclassified codes do not have associated billing units. Only 1 billing unit is entered in the respective claim form units field, even if multiple units are given. Billing with unclassified codes requires additional drug-identifying information to be submitted on the CMS-1500/837P and CMS-1450 (UB-04)/837I claim forms.

Site of care	Physician office, independent infusion center, home ²	HOPD ³
Claim form	CMS-1500/837P	CMS-1450 (UB-04)/837I
Claim form unit field	Item Number 24G (Loop 2400/SV104)	FL 46 (Loop 2400/SV2)
Claim form comment field	Item Number 19 (Loop 2400/SV101-7)	FL 80 (Loop 2300/NTE)
Additional drug information reported in the comment field^a	- Name of the drug (brand and generic) - Quantity of drug used (amount administered and amount discarded) - NDC in 11-digit format - Method of administration	

Key: FL – form locator; HOPD – hospital outpatient department; NDC – National Drug Code.

^a Check payer-specific reporting requirements. Information may be submitted as an attachment to the claim if field requirements prohibit all information from being included.



Accurate completion of claims is the sole responsibility of the HCP

HCPCS Modifiers

Modifiers to outpatient claims may be appropriate to provide payers with more information regarding services rendered. The following modifiers may potentially be applicable to ISEMBYLD. Other modifiers may apply check individual payer reporting requirements.

Modifier ^{1,4}	Description	Appropriate use
JW^{a, 5}	Drug amount discarded/not administered to any patient	Report modifier JW to indicate that some of the drug in a single-use vial is discarded. This requires 2 claim lines (required for Medicare fee-for-service claims; check other payer requirements)
JZ^{a, 5}	Zero drug amount discarded/not administered to any patient	Report modifier JZ to indicate that there was no drug wastage (required for Medicare claims; check other payer requirements)
SS	Home infusion services provided in the infusion suite of the IV therapy provider	May be appropriate for an ISEMBYLD home infusion that is administered at an infusion center rather than the patient's home. Check payer reporting requirements
TB	Drug or biological acquired with the 340B Drug Pricing Program discount, reported for informational purposes	Report modifier TB when ISEMBYLD is acquired through the 340B Drug Pricing Program (required for 340B-covered entities)
PN	Non-excepted service provided at an off-campus, outpatient, PBD of a hospital	Modifier PN is required on services from non-excepted off-campus PBDs
PO	Excepted service provided at an off-campus, outpatient, PBD of a hospital	Modifier PO is required on services from excepted off-campus PBDs of a hospital

Key: IV – intravenous; PBD – provider-based department.

^a Claims billed on the CMS-1500 are required to report the appropriate drug wastage modifier, and claims billed on the CMS-1450 do not require reporting drug wastage modifiers with unclassified codes. Check other payer reporting requirements.

National Drug Codes (NDCs)

NDCs are required on claims that include an unclassified HCPCS code for the product. For claims reporting, the Health Insurance Portability and Accountability Act (HIPAA) mandates converting the 10-digit NDC to an 11-digit format by adding a leading “0” (zero), as needed, to achieve the 5-4-2 configuration.⁶ The 11-digit NDC used to report ISEMBYLD in all sites of care is below:

11-digit billing NDC	Description ^{7,8}
84717-0150-01	One carton containing 150 mg/3 mL in a single-dose vial

Key: NDC – National Drug Code.



Accurate completion of claims is the sole responsibility of the HCP

Administration Service Codes

Current Procedural Terminology (CPT) codes define medical procedures performed by HCPs. The following codes may potentially be used to report the intravenous (IV) infusion of ISEMBYLD by an HCP:

CPT/HCPCS code ^{1,9}	Description	Appropriate use
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	May potentially be used for ISEMBYLD infusion for the initial 90 minutes of IV infusion
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	May potentially be used for ISEMBYLD IV infusion intervals greater than 30 minutes beyond 1-hour increments (ie, infusion must run at least 91 minutes)
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)	May potentially be used for ISEMBYLD home IV infusion. Check payer reporting requirements
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	

Key: CPT – Current Procedural Terminology; HCPCS – Healthcare Common Procedure Coding System; IV – intravenous.

Revenue Codes

Revenue codes are used by hospitals to identify the department in which services were provided, the types of services provided, and the supplies used. The following revenue codes may potentially be used to report ISEMBYLD and the IV infusion:

Item	Revenue code ¹⁰	Description
ISEMBYLD	0636	Drugs requiring detailed coding
IV infusion^a	0260	IV therapy, general
	0510	Clinic, general

Key: IV – intravenous.

^a Other revenue codes may apply.



Accurate completion of claims is the sole responsibility of the HCP

Place of Service (POS) Codes

HCPs use POS codes to identify the location where a service was performed on the CMS-1500 claim form. The outpatient POS codes below may potentially be appropriate for ISEMBYLD:

POS code ¹¹	POS name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
12	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence
19	Off-Campus Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
22	On-Campus Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
49	Independent Clinic	Location, not part of a hospital and not described by any other POS code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only

Key: POS – place of service.

Diagnosis Codes

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes report the patient-specific diagnosis documented in the medical record in all sites of care. The following ICD-10-CM codes may potentially be reported for SMA to support the medical necessity of ISEMBYLD treatment:

ICD-10-CM code ^{12,a}	Description
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.25	Progressive spinal muscle atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified

Key: ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification.

^a Report the ICD-10-CM code for spinal muscular atrophy at the highest level of specificity supported by the documentation in the medical record.



Accurate completion of claims is the sole responsibility of the HCP

Sample Professional Claim Form: CMS-1500 (837P), Physician Office/Independent Infusion Center

[illegible]

Useful Practices for Submitting ISEMBYLD Claims

Consider the following tips when submitting claims for ISEMBYLD. Complete and accurate claims help support timely claims processing, assist with appropriate reimbursement, and help reduce denials.



Ensure the patient's name, address, and insurance identification number are accurate



Include the HCP's name, National Provider Identifier (NPI), and payer-specific provider ID (if applicable)



Indicate the appropriate POS code (2-digit code) for where the treatment was provided on CMS-1500 professional claims



Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers are valid and consistent with information included in the patient's medical record



Ensure ISEMBYLD product-specific information is included in the appropriate comment field of the respective claim form

When submitting claims with an unclassified HCPCS code, additional documentation may be required by the payer for claims processing. Additional documentation may include:



**ISEMBYLD
prescribing information**



**Food and Drug
Administration
approval letter**



**Letter of
medical necessity**



**Patient
clinical notes**

This information may be submitted as an attachment to the claim.

References

- Centers for Medicare & Medicaid Services. January 2026 alpha-numeric HCPCS file. Accessed January 29, 2026. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
- Novitas Solutions. Paper to electronic claim crosswalk (5010) (CMS-1500). Accessed January 29, 2026. <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00004769>
- Novitas Solutions. Paper to electronic claim crosswalk (5010) (CMS-1450). Accessed January 29, 2026. <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00004768>
- Centers for Medicare & Medicaid Services. January 2017 update of the Hospital Outpatient Prospective Payment System (OPPS). Transmittal 3685. December 22, 2016. Accessed January 29, 2026. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3685CP.pdf>
- Centers for Medicare & Medicaid Services. Medicare program. Discarded drugs and biologicals – JW modifier and JZ modifier policy. Frequently asked questions. Accessed January 29, 2026. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>
- Cigna Healthcare. Coding guidelines for drug-related medical claims. Accessed January 29, 2026. <https://static.cigna.com/assets/chcp/resourceLibrary/medicalResourcesList/medicalDoingBusinessWithCigna/codingGuidelinesForDrugRelatedMedicalClaims.html>
- ISEMBYLD Prescribing information. Scholar Rock, 2026.
- Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26. Completing and processing the form CMS-1500 data set. August 9, 2024. Accessed January 29, 2026. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf>
- American Medical Association. 2026 CPT Professional Edition. Current Procedural Terminology (CPT®) copyright 2025 by the American Medical Association. All rights reserved. Chicago, IL: AMA; 2025.
- Noridian Healthcare Solutions. Revenue codes. Accessed January 29, 2026. <https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes>
- Centers for Medicare & Medicaid Services. Place of service code set. Updated May 2, 2024. Accessed January 29, 2026. <https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets>
- Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. Code tables, tabular, and index. Accessed January 29, 2026. <https://www.cms.gov/medicare/coding-billing/icd-10-codes>



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