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CODING AND

REIMBURSEMENT GUIDE

ICD-10-CM Diagnosis, HCPCS, CPT®, and NDC Billing Information for ANDEMBRY® (garadacimab-gxii)

CODING INFORMATION FOR ANDEMBRY® (garadacimab-gxii)

Disclaimers

- All codes provided are for informational purposes only and are subject to change without notice
- The treating physician is solely responsible for diagnosis coding and determination of the appropriate ICD-10-CM codes that describe the patient's condition and are supported by medical records
- Please contact third-party payers directly for specific information on their coding, coverage, payment policies, and fee schedules

For questions regarding reimbursement support, please call ANDEMBRY ConnectSM at 1-844-423-4273

ICD-10-CM Diagnosis Code for Persons With Hereditary Angioedema¹

ICD-10-CM Code	Description	
D84.1	Defects in the complement system C1 esterase inhibitor (C1-INH) deficiency	

HCPCS Codes²

The following drug codes have been assigned by the Center for Medicare and Medicaid Services (CMS) National Level II HCPCS coding system and can be used for ANDEMBRY. The provider is advised to verify the correct codes directly with the third-party payer.

HCPCS Code	Description
J3490	Unclassified drugs
J3590	Unclassified biologics

Note: These HCPCS codes are temporary and will be replaced by a permanent J-code once it is available.

HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

CPT® Administration Codes: Physician Office³

ANDEMBRY is a subcutaneous injection that may be self-administered or administered by a caregiver via a prefilled autoinjector subcutaneously into the thigh or abdomen, or to the upper arm if a caregiver administers the injection.

For Medicare beneficiaries, the following codes may not be payable. Medicare considers ANDEMBRY self-administered and therefore not covered as a Part B service. However, other payers may allow administration in a physician office or other site of service. The healthcare professional may not bill for the administration of ANDEMBRY if provided through the QuickStart Program.

Please verify current coding requirements directly with the payer being billed.

CPT® Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Do not report 96372 for injections given without direct physician or other qualified health professional supervision. To report, use 99211.

Note from CPT National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services: CPT code 96372 is reportable by physicians (MD, DO, or other practitioners who bill Medicare contractors) for services performed in physicians' offices. These drug administration services should not be reported by physicians for services provided in a facility setting such as a hospital outpatient, ambulatory surgery center, or emergency department.⁴

CPT® Code	Description	
99211	Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified healthcare professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.	

Note from CPT NCCI Policy Manual for Medicare Services: Drug administration CPT code 96372 has been valued to include the work and practice expenses of CPT code 99211. Therefore, CPT code 99211 is not reportable with CPT code 96372. Other non-facility—based evaluation and management codes may be separately reportable with modifier 25 if the physician provides a significant and separately identifiable E&M service.⁴

ANDEMBRY National Drug Codes (NDCs)

NDC (Device)	NDC (Carton)	Strength	Presentation
63833-925-20	63833-925-01	200 mg/1.2 mL	Prefilled autoinjector

CPT, current procedural terminology.



ANDEMBRY® (garadacimab-gxii) CMS-1500 CLAIM FORM

	HEALTH INSURANCE CLAIM FORM					
	APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12					
	MEDICARE MEDICAID TRICARE CHAMPV.	A GROUP FECA OTHER	1 a. INSURED'S I.D. NUMBER (For Program in Item 1)			
	(Medicare#) (Medicaid#) (ID#/DoD#) (Member II 2 PATIENT'S NAME (Last Name, First Name, Middle Initial)	O#) (IO#) (IO#) (IO#)	4. INSURED'S NAME (Last Name, First Name, Middle Initial)			
	2 PATIENT STRAINE (Last Name, Plist Name, Widdle Illiaa)	3. PATIENT'S BIRTH DATE SEX	4. INSOMED S NAME (Last Name, First Name, Middle IIII a)			
	5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)			
	CITY STATE	Self Spouse Child Other 8. RESERVED FOR NUCC USE	CITY STATE			
	TIDOODS AND THE STATE OF THE ST					
	ZIP CODE TELEPHONE (Include Area Code)		ZIP CODE TELEPHONE (Include Area Code)			
	9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER			
	a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH SEX			
		YES NO	a. INSURED'S DATE OF BIRTH SEX MM DD YY			
	b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)			
	c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR PROGRAM NAME			
	d. INSURANCE PLAN NAME OR PROGRAM NAME	YES NO				
	d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO #yes, complete items 9, 9a, and 9d.			
	READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. 12. PATIENT'S CR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necess		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier to			
	to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.		services described below.			
	SIGNED	SIGNED				
	MM DD YY	OTHER DATE AL. MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY			
	17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM , DD , YY			
_	17th 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	a NPI	FROM TO TO 20. OUTSIDE LAB? \$CHARGES			
L	15. ADDITIONAL SENIORINA CHINATION (DESignated by 14000)		YES NO			
	21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to servi	ice line below (24E) ICD Ind.	22. RESUBMISSION CODE ORIGINAL REF. NO.			
Н	A	D. L H. L	23. PRICR AUTHORIZATION NUMBER			
L	I. J. K.	L. L.				
	24. A. DATE(S) OF SERVICE	DURES, SERVICES, OR SUPPLIES E. DIAGNOSIS DIAGNOSIS POINTER POIN	F. G. H. I. J. DAYS EPSOT ID. RENDERING SCHARGES UNITS Pan QUAL PROVIDER ID. #			
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	24 CIONATURE OF PUVOICIAN OR CURRUES	YES NO	\$ \$			
	31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS () certify that the statements on the reverse apply to this bill and are made a part thereof.)	CILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ()			

Field 19: Additional Claim Information²

When an unclassified drug HCPCS code (J3490 or J3590) is used, the provider must include additional information about ANDEMBRY in a free-text field, such as Field 19 or its electronic equivalent. Payers typically require the name of the drug, its NDC, the route of administration, and the amount used for the treatment. For example:

- ANDEMBRY NDC (Device) 63833-925-20; Prefilled autoinjector; 200 mg/1.2 mL
- ANDEMBRY NDC (Carton) 63833-925-01; Prefilled autoinjector; 200 mg/1.2 mL

B Field 21: Diagnosis or Nature of Illness or Injury

Enter the ICD-10-CM diagnosis code(s) that best describes the reason the patient is receiving care.

C Field 24A (Shaded Area): NDC

For Medicaid claims and for Medicare claims that will cross over to Medicaid as the secondary payer, NDC information in a specific format is required in the shaded area above the line on which ANDEMBRY is reported in Field 24A. Various state Medicaid plans and Medicare have different reporting formats for this information.

Other payers may require different information. Check with the payer for specific requirements.

D Field 24D: CPT/HCPCS^{2,3}

HCPCS coding options for ANDEMBRY are:

- J3490 Unclassified drugs
- J3590 Unclassified biologics

For Medicare beneficiaries, the following code may not be payable:

• 96372: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

The code selected is based on the documented service provided to the patient.

Medicare considers ANDEMBRY self-administered and therefore not covered as a Part B service. However, other payers may allow administration in a physician office or other site of service. Please verify current coding requirements directly with the payer being billed.

Field 24E: Diagnosis Pointer

Enter the line number(s) from Field 21 that best describes the medical necessity for the service.

Field 24G: Days or Units

Requirements for Field 24G vary by payer. For example, some payers rely on the information in Field 19 for these data and request a placeholder of "1" in Field 24G. Other payers may require 1 unit per unit of drug used in the care of the patient.



Important Safety Information

ANDEMBRY® (garadacimab-gxii) injection, for subcutaneous use, is an activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

The most common adverse reactions in the pivotal trial (incidence \geq 7%) were nasopharyngitis and abdominal pain. In the pivotal trial and the open-label extension study, injection-site reactions (eg, injection-site bruising, injection-site erythema, injection-site hematoma, injection-site pruritus, injection-site urticaria) were reported in 23 (14%) patients.

No dedicated drug interaction studies have been conducted, nor is there data concerning the use of ANDEMBRY in women who are pregnant or breastfeeding. The safety and efficacy of ANDEMBRY in patients under 12 years of age have not been established.

<u>Drug Interference with Laboratory Test:</u> ANDEMBRY can prolong activated partial thromboplastin time (aPTT) due to an interaction of garadacimab-gxii with the aPTT assay.

Please see full Prescribing Information for ANDEMBRY.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full **Prescribing Information**.



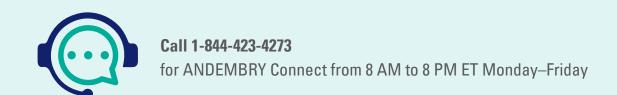
ANDEMBRY Connect provides ongoing, one-on-one support throughout the treatment journey

- Personalized support for each patient
- Dedicated case manager for each office
- Injection training and product support available through our dedicated nursing team
- Financial assistance*
- Benefits verification and prior authorization support (if applicable)

💳 QuickStart Program

ANDEMBRY QuickStart Program for commercially and government-insured patients

*Subject to terms and conditions of the copay assistance program. To read the full terms and conditions, visit http://cslbehring.com/patients/support-and-assistance. CSL Behring reserves the right to rescind, revoke, or amend the program at any time without notice.



References: 1. US Department of Health and Human Services, Centers for Medicare & Medicaid Services.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Accessed April 17, 2025.

https://www.cms.gov/medicare/coding-billing/icd-10-codes 2. US Department of Health and Human Services, Centers for Medicare and Medicaid Services. HCPCS release and code sets. Accessed April 17, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update 3. American Academy of Professional Coders. Accessed April 17, 2025. https://coder.aapc.com/cpt-codes 4. Medicaid NCCI 2023 Coding Policy Manual Chapter 11. Accessed April 17, 2025. https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2024-chapter-11.pdf

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