RUCONEST SOLUTIONS

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Billing and Coding Guide





Overview

RUCONEST® (C1 esterase inhibitor [recombinant]) is a biologic indicated for the treatment of acute attacks in adults and adolescent patients with hereditary angioedema. RUCONEST can be physician-administered or self-administered by an appropriately trained patient. This guide provides commonly used codes needed to submit a claim for the training and administration of RUCONEST by a healthcare professional.

Use of these codes may vary based on the setting of care and payer. Please check with individual payers to confirm specific billing and coding requirements.

Billing for RUCONEST

The HCPCS code to use when RUCONEST is purchased by your site and administered to a patient in your facility is J0596. The billable unit for J0596 is 10 international units (IU). There are 2100 IUs of drug in each vial. If 2 vials are administered to a patient, the number of units billed would be 420 billable units (ie, 4200 IUs / 10 = 420 billable units).

HCPCS Code ¹	Description
J0596	Injection, C1 esterase inhibitor (recombinant), RUCONEST, 10 units

Billing for Discarded Drug (Wastage)²

Most plans will pay for both the administered and discarded drug if specific criteria are met, including tracking of the wastage. Most plans will require separate line item billing for the amount administered and a separate line for the amount of product discarded. Typically, plans may request the use of the JW Modifier (drug or biological amount discarded/not administered to any patient).

Diagnosis Code

All claims should be submitted with the appropriate ICD-10-CM code.

Diagnosis Code ³		Description
ICD-10-CM	D84.1	Defects in the complement system

Depending upon the payer, E88.09 (Other disorders of plasma-protein metabolism, not elsewhere classified), may also be appropriate.

Billing for Administration Services

To report an IV injection service for RUCONEST, the following Current Procedural Terminology (CPT®) code may be appropriate.

CPT Code⁴	Description
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), IV push, single, or initial substance/drug



National Drug Code (NDC)

RUCONEST is supplied as 1 vial inside of 1 carton. The FDA assigned 2 unique NDCs for RUCONEST: 1 NDC for the vial and 1 NDC for the carton. For the purposes of billing or submitting claims, use the NDC on the carton. Please associate the 11-digit NDC code (no hyphens) with the HCPCS for RUCONEST in your billing system. Some payers may require that the NDC be preceded with a qualifier of N4. Payers may also request the unit of measure, number of units, and price per unit to be included.

NDC	Billing Format NDC	Container Type	Effective Date	
68012-350-02	68012035002	Carton	Until June 2017	
71274-350-02	71274035002	Carton	Pending June 2017	

Billing for Self-administration Training⁴

Evaluation & Management (E/M) codes may be used to bill for time spent providing self-administration training to a patient. Payer guidelines vary in terms of use of E/M codes and if there is separate payment available. The appropriate code should be determined based on factors such as the level of service provided and documented in the patient's medical record who provided the service, and the setting in which it was provided.

Use of Modifiers⁴

It may be necessary to append a modifier -25 when billing an E/M code in conjunction with the administration of RUCONEST.

Modifier	Description
-25	Distinct procedural service

Revenue Codes

Hospitals may use revenue codes to assign cost centers for related services and supplies. Below are examples of relevant revenue codes that may be appropriate for RUCONEST and its IV injection service. Use of these codes may vary based on the setting of care and payer. Please check with individual payers to confirm specific billing and coding requirements.

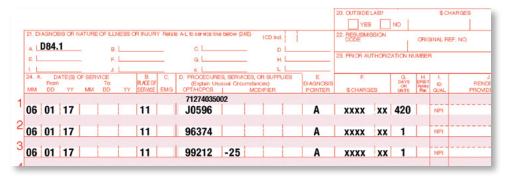
Revenue Code⁵	Description	Services
0636	Drugs requiring detailed coding	RUCONEST
0510	Clinic	Administration

This guide is intended to provide helpful information, but with a wide variety of payer and billing systems, users of this guide must verify the application of the codes. It is critical that billing reflect actual patient diagnosis and treatment. Healthcare providers are solely responsible for selecting and submitting appropriate codes, charges, and modifiers for services that are rendered and determining coverage, coding, and billing rules with payers. Please consult with your payers, reimbursement specialists, hospital policies, and/or legal counsel regarding proper coding, coverage, and reimbursement for these items and services.

Sample Claim Forms

Below are examples of hard copy claims for illustrative purposes only.

CMS-1500 Claim Form (Physician Office)



UB-04 Claim Form (Hospital Outpatient)

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES		48
1	0636	Drugs requiring detailed coding	J0596	06 01 17	420	xxxx	XX	П
2	0510	Clinic	96374	06 01 17	1	xxxx	XX	П
3								Ш
4								П
5								П
								4



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For information, call 1-855-613-4423

Please see Important Safety Information on the following pages and accompanying full Prescribing Information, including Patient Product Information here, or visit www.ruconest.com.

References

1. Centers for Medicare and Medicaid Services (CMS), 2017 Alpha-Numeric HCPCS File (rev'd Nov. 17, 2016). 2. See, eg, Centers for Medicare and Medicaid Services, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Section 40 – Discarded Drugs and Biologicals (effective Jan. 3, 2017). 3. National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) (2017). 4. AMA, Current Procedural Terminology (CPT®), Professional Edition (2017). CPT codes are copyright 2016 AMA. All rights reserved. 5. See, eg, Noridian Healthcare Solutions, Jurisdiction - Medicare Part A Revenue Codes (Feb. 14, 2017), available at: https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes.



