

COCAINE HYDROCHLORIDE NASAL SOLUTION, 4% (CII)

cocaine
hydrochloride nasal
solution, 4% (CII)

C-CODE FREQUENTLY ASKED QUESTIONS

1. What is a C-code?

A C-code is a unique Healthcare Common Procedure Coding System (HCPCS) code for use in the Medicare Part B Outpatient Prospective Payment System (OPPS). The C-codes (pass-through codes) were established to permit implementation of section 201 of the Balanced Budget Refinement Act of 1999. HCPCS C-codes are used to report drugs, biologicals, magnetic resonance angiography (MRA), and devices used for CMS's Medicare Hospital Outpatient Prospective Payment System (HOPPS). HCPCS C-codes are reported for device categories, new technology procedures, and drugs, biologicals, and radiopharmaceuticals that do not have other HCPCS code assignments. Non-OPPS hospitals, Critical Access Hospitals (CAHs), Indian Health Service hospitals (IHS), and hospitals located in American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands, as well as Maryland waiver hospitals, may report these codes at their discretion.¹ For information about the HOPPS pass-through process, please visit the HOPPS web site: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS>

While pass-through status will last for up to three years, once a product receives a permanent J-Code, the C-code is no longer used and has no effect on pass-through status.

Hospital outpatient departments and ambulatory surgical centers may bill using the C-code for FFS Medicare patients.¹

2. Who issues the C-code?

HCPCS codes are established by the Centers for Medicare & Medicaid Services (CMS).²

3. Does cocaine hydrochloride nasal solution, 4% (CII) have a C-code?

Yes. C9046, "Cocaine hydrochloride nasal solution for topical administration, 1 mg," is available for use for dates of service on or after April 1, 2019.³

4. Are there other products crosswalked to C9046?

No. C9046 is authorized only for cocaine hydrochloride nasal solution, 4% (CII) (National Drug Code 64950-0362-04).³

1 Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>. Accessed December 4, 2019.

2 Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets. 2020. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2020-Alpha-Numeric-HCPCS-File.zip>. Accessed November 8, 2019.

3 Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets. April 1, 2019. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed December 4, 2019.

4 April 2019 Update of the Ambulatory Surgical Center (ASC) Payment System. MLN Matters Number: MM11232. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11232.pdf>. Accessed December 4, 2019.

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5. Which payer segments accept C-codes?

C-codes are used to report claims primarily in the Medicare Hospital Outpatient OPPS setting.⁵ Other non-Medicare payers may not recognize C-codes. Please consult individual payer requirements. In some cases J3490 Not Otherwise Classified Drug code may be used.

6. What are the appropriate billing units for cocaine hydrochloride nasal solution, 4% (CII)?

Cocaine hydrochloride nasal solution, 4% (CII) is supplied in a single-use 4 mL bottle with 160 mg/4 mL (40 mg/mL or 4%) cocaine hydrochloride, equivalent to 142.4 mg/4 mL (35.6 mg/mL) cocaine free-base.⁶

C9046 is for cocaine hydrochloride nasal solution for topical administration, 1 mg. This means there are 160 billing units in a single-use vial of cocaine hydrochloride nasal solution, 4% (CII).

7. How do health plans get notified about the new C-code?

Most insurance plans, including Medicare and Medicaid, update HCPCS codes quarterly in alignment with the CMS code release effective dates. This is a manual process and some payers may not update immediately.

The HCPCS release and code sets can be found in the Alpha-Numeric HCPCS File on the CMS website at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>.

8. Are electronic medical records (EMRs) automatically updated with the new J-Code?

EMR vendors typically update their system with the new HCPCS codes in sync with the CMS quarterly release and effective dates. Some EMRs need to be updated manually if the EMR vendor does not provide the update service.^{1,3,7} This enables automatic versus manual processing of claims, which may reduce errors and can lead to timely reimbursement. In turn, providers feel more confident about drug access.^{1,3,8}

9. Are miscellaneous codes used to bill for cocaine hydrochloride nasal solution, 4% (CII)?

The following codes can be used until the permanent HCPCS code has been assigned, when billing to other payers or non-OPPS hospital settings of care.

- J3490 Unclassified drug

In order to ensure prompt processing, please remember to include the following information: NDC code, drug name, dose of product, quantity administered, route of administration, packaging (i.e., single-dose vial), and indication.

5 Medical Billing and Coding Certification. HCPCS codes. <https://www.medicalbillingandcoding.org/hcpcs-codes/>. Accessed November 21, 2019.

6 Genus Lifesciences. Cocaine Hydrochloride Nasal Solution, 4% (CII) Prescribing Information. <http://genusagcocaine.com/agcocaine.pdf>. Accessed November 21, 2019.

7 Athena Health. Why choose us. MACRA and MIPS. <https://www.athenahealth.com/why-choose-us/macra-and-mips>. Accessed November 19, 2019.

8 HealthIT.gov. Medical Practice Efficiencies & Cost Savings. <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/medical-practice-efficiencies-cost-savings>. Accessed November 19, 2019.

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INDICATIONS AND USAGE

Cocaine hydrochloride nasal solution is an ester local anesthetic indicated for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.

IMPORTANT SAFETY INFORMATION

Cocaine hydrochloride nasal solution is a Schedule II controlled substance.

WARNING: ABUSE AND DEPENDENCE. CNS stimulants, including cocaine hydrochloride, have a high potential for abuse and dependence.

CONTRAINDICATIONS

Known hypersensitivity to cocaine hydrochloride, other ester-based anesthetics, or any other component of cocaine hydrochloride.

WARNINGS AND PRECAUTIONS

Seizures: Cocaine hydrochloride may lower the convulsive threshold. Monitor patients for development of seizures.

Blood Pressure and Heart Rate Increases: Monitor vital signs, including heart rate and rhythm, in patients after receiving cocaine hydrochloride. Avoid use of cocaine hydrochloride in patients with a recent or active history of uncontrolled hypertension, unstable angina, myocardial infarction, coronary artery disease, or congestive heart failure.

Toxicology Screening: Cocaine hydrochloride and its metabolites may be detected in plasma for up to one week after administration and in urine toxicology screening for longer than one week after administration.

ADVERSE REACTIONS

The most common adverse reactions (>0.5%) occurring in patients treated with cocaine hydrochloride were headache and epistaxis.

DRUG INTERACTIONS

Disulfiram: Increases plasma cocaine exposure. Avoid using cocaine hydrochloride in patients taking disulfiram.

Epinephrine, Phenylephrine: There have been reports of myocardial ischemia, myocardial infarction, and ventricular arrhythmias with concomitant use during nasal surgery. Avoid use of additional vasoconstrictor agents with cocaine hydrochloride nasal solution. If concomitant use is unavoidable, prolonged vital sign and ECG monitoring may be required.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm.

Lactation: Avoid breastfeeding during treatment with cocaine hydrochloride; pump and discard breastmilk for 48 hours after treatment.

Hepatic Impairment: Monitor for adverse reactions such as headache, epistaxis, and clinically relevant increases in heart rate or blood pressure. Do not administer a second dose within 24 hours of the first dose.

OVERDOSAGE

No cases of overdose with cocaine hydrochloride were reported in clinical trials. In the case of an overdose, consult with a certified poison control center (1-800-222-1222) for up-to-date guidance and advice for treatment of overdose. Individual patient response to cocaine varies widely. Toxic symptoms may occur idiosyncratically at low doses.

Please note that this information is not comprehensive. Please visit www.GenusCocaine.com for the full prescribing information for cocaine hydrochloride nasal solution, 4% (CII).

To report SUSPECTED ADVERSE REACTIONS, contact Pharm-Olam at 1-866-511-6754 or the FDA at 1-800-FDA-1088 or through www.fda.gov/medwatch.