SAMPLE CODING AND BILLING REFERENCE SHEET FOR THE MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

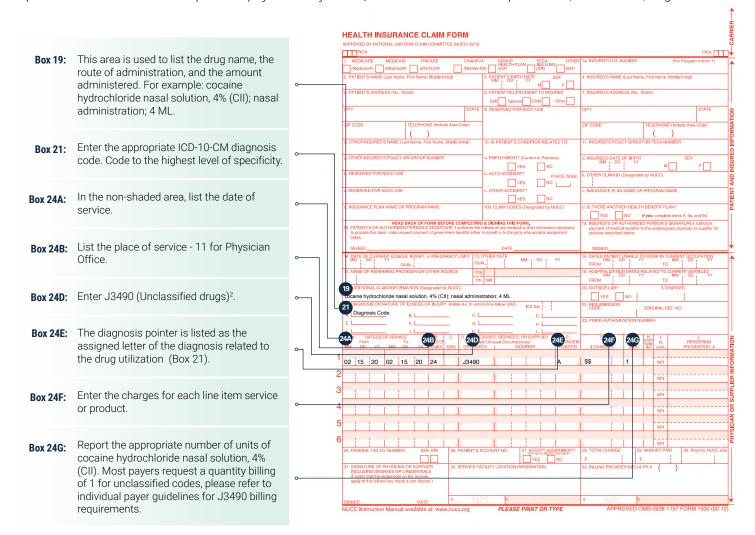
cocaine hydrochloride nasal solution, 4% (CII)

PHYSICIAN OFFICE SETTING

Sample CMS-1500 claim form for cocaine hydrochloride nasal solution, 4% (CII)¹

Although this sheet provides information that should facilitate the claims process, all coding information is for reference purposes only. Genus Lifesciences does not guarantee payment.

The healthcare billing environment is constantly evolving to keep pace with scientific advances and financial constraints. Information specific to billing and coding is subject to change and should be verified for each patient prior to treatment. A provider should contact their patient's payer directly for any revised or additional requirements, information, or guidance.



IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist healthcare providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

¹ Centers for Medicare & Medicaid Services. CMS Manual System. Details for title: CMS-1500. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms/ltems/CMS1188854. Accessed November 14, 2019.

² Find-A-Code. J3490. Unclassified drugs. https://www.findacode.com/code.php?set=HCPCS&c=J3490. Accessed February 4, 2020.

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 overdosage. 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.

