# C-CODE NOW AVAILABLE FOR COCAINE HYDROCHLORIDE NASAL SOLUTION, 4% (CII)

C9046 Cocaine hydrochloride nasal solution for topical administration, 1 mg

cocaine hydrochloride nasal solution, 4% (CII)

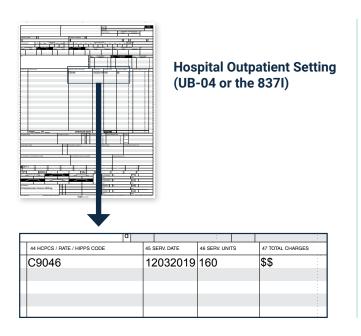
# AMBULATORY SURGICAL CENTER SETTING

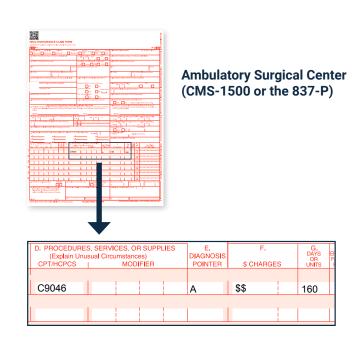
Cocaine hydrochloride nasal solution, 4% (CII) was granted transitional pass-through status, effective April 1, 2019. Transitional pass-through status is a temporary payment granted by the Centers for Medicare & Medicaid Services (CMS). When a drug is granted pass-through status by CMS, outpatient facilities are eligible to receive separate payment for the pass-through drug in addition to the payment received for procedures furnished during the patient encounter. Pass-through status remains in effect for 2 to 3 years. Pass-through status is applicable to Medicare patients only.<sup>2</sup>

In addition, C9046 has been identified as a drug code eligible to be paid separately when provided integral to a surgical procedure on the ambulatory surgical center (ASC) list; payment is based on hospital outpatient prospective payment system rates.<sup>3</sup>

Commercial plans may or may not follow CMS policy for ASC claim filing or reimbursement payments. Please consult individual payer requirements.

Each 1 mg dose of cocaine hydrochloride nasal solution, 4% (CII) equals one billing unit, thus 160 mg/4 mL (40 mg/mL, or 4%) in a single-dose mixed vial represents 160 units of C9046. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment.





- 1 Centers for Medicare and Medicaid Services. HCPCS Release & Code Sets. April 1, 2019. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed December 3, 2019.
- 2 Medicare Prospective Payment System for Hospital Outpatient Service, Final Rule. 65 FR 18478. April 7, 2000.
- 3 April 2019 Update of the Ambulatory Surgical Center (ASC) Payment System. MLN Matters Number: MM11232. <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11232.pdf">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11232.pdf</a>. Accessed December 3, 2019.

**IMPORTANT INFORMATION:** The coding and payment information herein is general in nature, does not constitute legal advice, and is not intended to increase or maximize reimbursement. It is the provider's responsibility to determine the appropriate treatment, coverage, reimbursement, and appropriate coding for a particular patient and/or procedure. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

# **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 <a href="https://www.GenusCocaine.com">www.GenusCocaine.com</a> 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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.

