

CAUTION: Read the [ICD-9 Policy Holding Library](#) page about policy in this document.

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Non-Injectable Drugs

This section includes information about billing for non-injectable drug services.

NDC Billing Requirement

The Federal Deficit Reduction Act of 2005 (DRA) requires collection of rebates from drug manufacturers for physician-administered drugs. This policy may affect the billing of non-injectable drugs. Before submitting claims for non-injectable drugs, providers should review important NDC billing instructions in the *Physician-Administered Drugs – NDC* section of this manual.

Treatment Policy for the Management of Chronic Hepatitis C

This policy was developed by the Department of Health Care Services (DHCS) based on a review of the medical literature, the most recent guidelines and reports published by:

- American Association for the Study of Liver Diseases (AASLD)
- Infectious Diseases Society of America (IDSA)
- European Association for the Study of the Liver (EASL)
- California Technology Assessment Forum (CTAF)
- Institute for Clinical and Economic Review (ICER)
- World Health Organization (WHO)
- federal Department of Veterans Affairs (VA)
- and recommendations from experts in the management of hepatitis C virus

The treatment of hepatitis C virus is rapidly evolving. Accordingly, this policy may be revised as new information becomes available.

Treatment Considerations and Choice of Regimen for Hepatitis C Virus Infected Patients

Please refer to AASLD guidelines (hcvguidelines.org) for treatment regimens and durations.

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Identifying Treatment
Candidates

Disease Prognosis and Severity – Any of the following clinical states identify candidates for treatment:

- Evidence of Stage 2 or greater hepatic fibrosis/cirrhosis including one of the following:
 - Liver biopsy confirming a METAVIR score F2 or greater
 - Transient elastography (Fibroscan®) score greater than or equal to 7.5 kPa
 - FibroSure® score of greater than or equal to 0.48
 - APRI score greater than 0.7
 - FIB-4 greater than 0.35.
- Evidence of extra-hepatic manifestation of hepatitis C virus, such as type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), or kidney disease (e.g. proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis)
- Persons with hepatocellular carcinoma with a life expectancy of greater than 12 months
- Pre- and post-liver transplant, or other solid organ transplant
- HIV-1 co-infection
- Hepatitis B co-infection
- Other coexistent liver disease (e.g. nonalcoholic steatohepatitis)
- Type 2 diabetes mellitus (insulin resistant)
- Porphyria cutanea tarda
- Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)
- Men who have sex with men with high-risk sexual practices
- Active injection drug users
- Persons on long-term hemodialysis
- Women of childbearing age who wish to get pregnant
- HCV-infected health care workers who perform exposure-prone procedures

Patient Readiness and Adherence	<ol style="list-style-type: none">1. Patients shall be evaluated for readiness to initiate treatment.2. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.3. Caution shall be exercised with patients who have a history of treatment failure with prior hepatitis C treatment due to non-adherence with treatment regimen and appointments. Patients shall be educated regarding potential risks and benefits of hepatitis C virus therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.
Age Requirements	Treatment candidate must be 18 years of age or older.
Quantity Limits	Prescription of hepatitis C therapy will be dispensed in quantities up to 28 days at a time.
Criteria for Reauthorization/Continuation of Therapy	<ol style="list-style-type: none">1. Initial authorization criteria have been met, and2. Evidence of lack of adherence may result in denial of treatment reauthorization.3. Missed medical appointments related to the hepatitis C virus may result in denial of treatment authorization.
Laboratory Testing	<ol style="list-style-type: none">1. Documentation of baseline hepatitis C virus-RNA level2. Documentation of hepatitis C virus Genotype3. Laboratory testing should be consistent with current AASLD/IDSA guidelines.

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Populations Unlikely to Benefit from Hepatitis C Virus Treatment

According to AASLD/IDSA hepatitis C virus Guidelines, “patients with limited life expectancy for whom hepatitis C virus therapy would not improve symptoms or prognosis do not require treatment. Chronic hepatitis C is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of hepatitis C virus treatment in patients with limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. For these patients, the benefits of hepatitis C virus treatment are unlikely to be realized, and palliative care strategies should take precedence.” In patients with a life expectancy less than 12 months, treatment is not recommended.

Retreatment

Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).

Criteria for Coverage of Investigational Services (Title 22 § 51303)

Investigational services are not covered except when it is clearly documented that all of the following apply:

- Conventional therapy will not adequately treat the intended patient's condition;
- Conventional therapy will not prevent progressive disability or premature death;
- The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
- The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;
- The service is not being performed as a part of a research study protocol;
- There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living;
- All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

Unlabeled Use of Medication	<p>Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:</p> <ul style="list-style-type: none"> • Reference to current medical literature. • Consultation with provider organizations, academic and professional specialists.
Ganciclovir Long-Acting Implant	<p>The ganciclovir, 4.5 mg, long-acting implant is billed with HCPCS code J7310 for the treatment of cytomegalovirus (CMV) retinitis in recipients with AIDS.</p> <p>The insertion of the implant should be performed by a board-certified ophthalmologist who is trained in this procedure. Each ganciclovir long-acting implant contains a minimum of 4.5 mg of ganciclovir and is designed to slowly release ganciclovir into the vitreous cavity over a period of five to eight months. The implants are usually replaced electively at seven to eight months. However, the implant may be replaced earlier if the depletion of ganciclovir from the implant occurs, as evidenced by progression of retinitis.</p>
Billing	<p>The ganciclovir long-acting implant is reimbursable when billed in conjunction with ICD-9-CM codes 078.5 (cytomegaloviral disease) or codes 363.00 – 363.35 (chorioretinitis). The implantation procedure is billed using CPT-4 code 67027 (implantation of intravitreal drug delivery system [e.g., ganciclovir implant], includes concomitant removal of vitreous) and is reimbursable to the ophthalmologic surgeon who performs the insertion or to the surgeon's employer, such as an eye clinic or hospital outpatient department. One ganciclovir long-acting implant is reimbursed per recipient in any six-month period. Additional implants may be reimbursed if documented medical justification accompanies the claim such as, but not limited to, one of the following:</p> <ul style="list-style-type: none"> • The recipient requires an implant in both eyes. • The implant becomes depleted of ganciclovir and needs to be replaced. • It is time for elective replacement of the implant. • The recipient has developed an infection and/or complication.

Patients with a ganciclovir long-lasting implant in one eye may still require systemic coverage with either ganciclovir or foscarnet to protect the contralateral, uninvolved eye. Ganciclovir administered intravenously will not be approved for longer than 30 days following the insertion of a ganciclovir implant unless documentation of medical justification is entered in the *Remarks* field (Box 80)/*Reserved for Local Use* field (Box 19) of the claim or on an attachment. Patients with bilateral retinal disease and a ganciclovir long-lasting implant in both eyes may not require oral or intravenous therapy unless there is evidence of previous pulmonary, gastrointestinal or other systemic CMV disease.

Azithromycin for Chlamydia

Physicians, nurse practitioners or nurse midwives may be reimbursed for azithromycin when provided for the treatment of chlamydial infections of the cervix or urethra.

Required codes

Required ICD-9-CM codes are as follows:

- Urethritis 099.41
- Cervicitis 099.53 and 616.0

Billing

HCPCS code

Q0144 (azithromycin dihydrate, oral, capsules/powder, 1 gram)

For the diagnoses above, providers may be reimbursed for a maximum of 1 gram of azithromycin per recipient and date of service.

Albuterol	Claims for albuterol inhalation solution (HCPCS code J7611) billed in excess of 30 mg require documentation of continued airflow obstruction.
Granisetron (Oral Tablets)	<p>Granisetron hydrochloride is indicated for the prevention of:</p> <ul style="list-style-type: none"> • Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin. • Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.
Dosing	The recommended adult dosage of oral granisetron hydrochloride is 2 mg once daily or 1 mg twice daily. In the 2 mg once-daily regimen, the 2 mg dose is given up to 1 hour before chemotherapy. In the 1 mg twice-daily regimen, the first 1 mg dose is given up to 1 hour before chemotherapy, and the second dose is given 12 hours after the first. Either regimen is administered only on the day(s) chemotherapy is given.
Billing	HCPCS code Q0166 (granisetron hydrochloride, 1 mg, oral)
Histrelin Vantas	Histrelin implant, 50 mg, (HCPCS code J9225, Vantas), for the treatment of males 30 years of age or older with prostate cancer, is reimbursable when billed with ICD-9-CM diagnosis code 185. Coverage is limited to one in 12 months.
Histrelin Supprelin LA	Histrelin implant, 50 mg, (HCPCS code J9226, Supprelin LA), is used for the treatment of precocious puberty in children aged 2 – 15 years. Claims may be reimbursed when billed in conjunction with ICD-9-CM diagnosis code 259.1. Coverage is limited to one in 12 months.
Dornase Alfa	HCPCS code J7639 (dornase alfa, 1 mg, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, per mg) must be billed with ICD-9-CM codes 227.0 – 277.09. Maximum dosage is 2 mg.

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**Testosterone Pellet
(Testopel)**

Testosterone pellet (Testopel), 75 mg, (HCPCS code S0189) is used for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Code S0189 is restricted to males only.

Required Codes

Claims for code S0189 must be billed in conjunction with ICD-9-CM diagnosis code 257.2, 257.8 or 257.9.

Dosage

Maximum dosage is 450 mg every 90 days.

**Formoterol Fumarate
(Perforomist™)**

For HCPCS code J7606 (formoterol fumarate, inhalation solution, 20 mcg), when billing for a quantity greater than two (40 mcg), providers must document that either the recipient's weight requires a higher dose or that there is a continued airway obstruction.

Capsaicin Patch

The capsaicin patch is reimbursable for treatment of post-herpetic neuralgia for recipients 18 years of age and older.

Required Codes

ICD-9-CM diagnosis codes 053.10 – 053.19

Billing

HCPCS code J7335 (capsaicin 8% patch, per 10 square centimeters)

**Lidocaine and Tetracaine
Patch**

Claims for C9285 (lidocaine 70 mg/tetracaine 70 mg, per patch) billed in excess of 2 patches per day require an approved *Treatment Authorization Request* (TAR) for reimbursement.

Mannitol

Claims for J7665 (mannitol, administered through an inhaler, 5 mg) billed in excess of 635 mg (127 units) require authorization.