Non-Injectable Drugs

This section includes information, «sorted alphabetically,» 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 National Drug Code (NDC) billing instructions in the Physician-Administered Drugs – NDC section of this manual.

Albuterol

Claims for albuterol inhalation solution (HCPCS code J7611) billed in excess of 30 mg require documentation of continued airflow obstruction.

Aminolevulinic Acid 10% Gel

Aminolevulinic acid 10% gel, is a porphyrin precursor, used in combination with photodynamic therapy using BF-RhodoLED lamp. Photoactivation following topical application of Ameluz® occurs when aminolevulinic acid (prodrug) is metabolized to protoporphyrin IX (PpIX), a photoactive compound which accumulates in the skin. When exposed to red light of a suitable wavelength and energy, PpIX is activated resulting in an excited state of porphyrin molecules. In the presence of oxygen, reactive oxygen species are formed which causes damage to cellular components, and eventually destroys the cells.

Indication

Aminolevulinic acid 10% gel is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp for patients 18 years of age and older.
Dosage
Administer Ameluz only by a health care provider.

- Ameluz is for topical use only
- Photodynamic therapy with Ameluz involves preparation of lesions, application of the product, occlusion and illumination with BF-RhodoLED.
- Retreat lesions that have not completely resolved 3 months after the initial treatment
- See BF-RhodoLED user manual for detailed lamp safety and operating instructions

Authorization
A Treatment Authorization Request (TAR) is required for reimbursement.

Required Codes
ICD-10-CM diagnosis code L57.0

Billing
HCPCS code J7345 (aminolevulinic acid HCl for topical administration, 10% gel, 10 mg)

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-10-CM codes are as follows:

- Chlamydial infection of lower genitourinary tract A56.01, A56.09

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 patient and date of service.
Bupivacaine and Meloxicam (Zynrelef™)

Zynrelef is a fixed-dose combination of bupivacaine and meloxicam.

**Bupivacaine**

Local anesthetics block the generation and the conduction of nerve impulses presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone.

**Meloxicam**

The mechanism of action of meloxicam, like that of other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Meloxicam is a potent inhibitor of prostaglandin synthesis in vitro. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because meloxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

**Indications**

All FDA-approved indications

**Dosage**

FDA-approved dosages

**TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.
TAR Criteria
Zynrelef is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Medication is being used to produce postsurgical analgesia and it has not been more than 72 hours since surgery
- Patient had one of the following surgeries:
  - Bunionectomy
  - Open inguinal herniorrhaphy
  - Total knee arthroplasty
- Patient will not use local anesthetics within 96 hours of administration
- Patient does not have a known hypersensitivity (for example, anaphylactic reactions and serious skin reactions) to any amide local anesthetic
- Patient does not have a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
- Patient is not undergoing obstetrical paracervical block anesthesia
- Patient is not undergoing coronary artery bypass graft (CABG) surgery

Authorization is for a single-dose administration

Age Limits
Must be 18 years of age or older.

Billing
HCPCS code C9088 (instillation, bupivacaine and meloxicam, 1 mg/0.03 mg).

Prescribing Restriction(s)
Frequency of billing equals 400 mg/12 mg /400 units as a single dose.
Maximum billing units equals 400 mg/12 mg /400 units
Buprenorphine Implant

Buprenorphine implant is a partial opioid agonist for subdermal administration. Each implant is 26 mm in length and 2.5 mm in diameter and contains 74.2 mg of buprenorphine (equivalent to 80 mg of buprenorphine hydrochloride) and ethylene vinyl acetate (EVA).

Indications

Buprenorphine implant is reimbursable for the maintenance treatment of moderate or severe opioid dependence in patients who have already started buprenorphine therapy with dose titration and stabilization for greater than or equal to 7 days.

Buprenorphine implant is used as part of a comprehensive treatment program including psychosocial counseling, support and regular, frequent office visits to continually evaluate and monitor the patient’s progress.

Comprehensive treatment program best-practice guidelines are described in, but are not limited to, the following references:

- *Federal Guidelines for Opioid Treatment Programs* by the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services, 2015;
- *ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* by the American Society of Medicine, 2015;
- *Practice Guideline for the Treatment of Patients with Substance Use Disorders, Second Edition* by the American Psychiatric Association (APA), 2010;

A prescribing physician, nurse practitioner or physician assistant must hold a current state medical practitioner license number, a regular U.S. Drug Enforcement Agency (DEA) controlled substance registration number and a special SAHMSA waiver DEA identification number. Prescription use is limited under the Drug Addiction Treatment Act of 2000 (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114-198, Title III, Section 303).

Due to the risk of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of the implant, buprenorphine implant is only available through a restricted distribution program called the Probuphine® Risk Evaluation and Mitigation Strategy (REMS) Program. Healthcare providers who prescribe, insert and remove buprenorphine implant must be certified with the Probuphine® REMS Program.
Age
16 years and older

Dosage
After induction, titration and stabilization with a buprenorphine transmucosal formulation for greater than or equal to 7 days, the recommended dose of four buprenorphine implants is inserted sub-dermally into the inner side of an upper arm. The implants release up to six months of buprenorphine treatment until removal by the end of the sixth month. A subsequent dose may be administered in the contralateral arm, but buprenorphine implants should not be used beyond a single insertion per arm.

Authorization
An approved Treatment Authorization Request (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates medical necessity for maintenance treatment of moderate or severe opioid use disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders – Version 5 (DSM-5) by the presence of 4 or more symptom criteria for opioid use disorder within a 12-month period:

- The diagnosis has been confirmed by a comprehensive assessment including but not limited to a medical history and physical examination, objective clinical scales that measure symptoms of withdrawal, psychosocial and functional impairment, laboratory testing data, etc.
- The service is part of a comprehensive treatment program including psychosocial treatment and regular, frequent office visits to continually evaluate and monitor the patient’s progress.
- The patient has voluntarily demonstrated the motivation and ability to participate in maintenance treatment for opioid use disorder.
- The patient is currently on a dose of 8 to 24 mg per day of a buprenorphine transmucosal formulation for seven or more days.
- The treating practitioner’s completed order/treatment plan/procedure note for buprenorphine implant, including the practitioner’s current CA medical license, regular U.S. Drug Enforcement Agency (DEA) registration control number and special Substance Abuse and Mental Health Services Administration (SAMHSA) waiver DEA identification number.
Required Codes
One of the following ICD-10-CM diagnosis codes is required for reimbursement:

- F11.20 (opioid dependence, uncomplicated)
- F11.21 (opioid dependence, in remission)
- F11.24 (opioid dependence with opioid-induced mood disorder)
- F11.250 (opioid dependence with opioid-induced psychotic disorder with delusions)
- F11.251 (opioid dependence with opioid-induced psychotic disorder with hallucinations)
- F11.259 (opioid dependence with opioid-induced psychotic disorder, unspecified)
- F11.281 (opioid dependence with opioid-induced sexual dysfunction)
- F11.282 (opioid dependence with opioid-induced sleep disorder)
- F11.288 (opioid dependence with other opioid-induced disorder)
- F11.29 (opioid dependence with unspecified opioid-induced disorder)

Billing
HCPCS code J0570 (buprenorphine implant, 74.2 mg)
One (1) unit of J0570 = a single 74.2 mg buprenorphine implant

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

Required Codes
ICD-10-CM diagnosis codes B02.21 through B02.23

Billing
HCPCS code J7336 (capsaicin 8% patch, per square centimeter)
Cinacalcet Tablets (Sensipar®)

Sensipar is an oral calcimimetic medication that lowers the levels of parathyroid hormone (PTH), phosphorous and calcium in patients undergoing kidney dialysis or in patients with parathyroid cancer. The calcium-sensing receptor on the surface of the chief cell of the parathyroid gland is the principal regulator of PTH synthesis and secretion. Cinacalcet, the active ingredient in Sensipar, directly lowers PTH levels by increasing the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved Treatment Authorization Request (TAR) is required for reimbursement.

TAR Criteria

«Initial Therapy»

Sensipar will be considered medically necessary when the following criteria are met:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following
  1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD) and is on dialysis
     - Current lab results show intact parathyroid hormone (iPTH) and serum calcium levels above the normal range
  2. Hypercalcemia with parathyroid carcinoma (PC)
  3. Hypercalcemia with primary hyperparathyroidism (HPT) and unable to undergo parathyroidectomy
     - Calcium greater than 12.5 mg/dL
- Prescriber to monitor calcium levels periodically throughout therapy

Initial approval is for 6 months

Part 2 – Non-Injectable Drugs
Continued therapy:

- Patient is responding positively to therapy as evidenced by a decrease in iPTH (for secondary HPT) or a decrease in serum calcium level (for PC or primary HPT); and
- Patient’s serum calcium level is not less than the lower limit of normal

Reauthorization is for 12 months.

Age Limits

Must be 18 year of age or older

Billing

HCPCS code, J0604, Cinacalcet, oral, 1 mg, (for ESRD on dialysis)

Prescribing Restrictions

Frequency of billing = every 24 hours
Maximum billing unit(s) = 360 mg/360 units

Ciprofloxacin Otic Solution

Ciprofloxacin is a quinolone antimicrobial. Quinolones rapidly inhibit DNA synthesis by promoting cleavage of bacterial DNA in the DNA-enzyme complexes of DNA gyrase and type IV topoisomerase, resulting in rapid bacterial death.

Indications

Ciprofloxacin otic solution is a quinolone antimicrobial indicated for the treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.
Authorization

An approved Treatment Authorization Request (TAR) is required for reimbursement. The TAR must state that the patient has otitis externus due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.

Dosage

Contents of one single-use container should be instilled into the affected ear twice daily (approximately 12 hours apart) for seven days.

Required Code

ICD-10-CM diagnosis code H60.20

Billing

HCPCS code J7342 (installation, ciprofloxacin otic suspension, 6 mg)

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-10-CM codes E84.0 through E84.9. Maximum dosage is 2 mg.

Esketamine Nasal Spray (Spravato®)

Esketamine, the S-enantiomer of racemic ketamine, is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. The mechanism by which esketamine exerts its antidepressant effect is unknown. The major circulating metabolite of esketamine (noresketamine) demonstrated activity at the same receptor with less affinity.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages
TAR Requirement

An approved Treatment Authorization Request (TAR) is required for reimbursement.

TAR Criteria

«Initial Therapy»

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following:
  - Treatment-resistant depression (TRD)
  - Major depressive disorder (MDD) with acute suicidal ideation or behavior
- Diagnosis must be confirmed by baseline depression assessment using any validated rating scale
- Must be prescribed by or in consultation with a psychiatrist or other specialist in the treatment of the disease

A. Treatment-Resistant Depression (TRD)

Must meet the following criteria:

1. Diagnosis of Major Depressive Disorder (MDD) by Diagnostic and Statistical Manual of Mental Disorders - Version 5 (DSM-5) diagnostic criteria;

2. Patient must meet the DSM-5 diagnostic criteria for single-episode major depressive disorder (MDD) (if single-episode MDD, the duration must be two years or more) or recurrent MDD, without psychotic features, based upon clinical assessment.

3. Must have a documentation of inadequate response with a therapeutic trial of two or more antidepressants from different classes, given at adequate dose and duration (at least six weeks), including in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced. Inadequate response is defined as less than or equal to 25 percent reduction on Montgomery-Asberg Depression Rating Scale (MADRS) with minimum score greater than or equal to 28 for adults, or greater than or equal to 24 for geriatrics).
4. Must have a documented therapeutic trial (duration of at least six weeks) of antidepressant augmentation therapy in the current depressive episode with one or more of the following, unless contraindicated, clinically significant adverse effects are experienced, or patient is at high risk for suicidality:
   I. Atypical antipsychotic
   II. Lithium
   III. Antidepressant from a different class used in the previous therapeutic trials
   IV. Electroconvulsive therapy
   V. Transcranial Magnetic Stimulation (TMS)

B. Depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior.
Must meet the following criteria:
1. Patient has a severe depressive episode (cannot care for self, participate in life, has persistent thoughts of hopelessness, persistently sad, anxious or has an "empty" mood, thoughts of suicide, etc.)
2. Provider has attested that acute psychiatric hospitalization is clinically warranted due to patient's imminent risk of suicide

«As well as the following for both diagnoses (B1 and B2)»
• Patient must have documentation of concurrent antidepressant therapy
• Prescriber must attest that:
  − An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified
  − Dosing schedule has been reviewed with the patient
  − The patient understands and is committed to dosing schedule and requirements (for example, treatment visits, transportation)
• Patient does not have any of the following conditions:
  − Pregnancy
  − History of psychotic disorder (including MDD with psychotic symptoms), bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, borderline personality disorder, dementia or intellectual disability.
  − Other major medical conditions including coronary artery disease.

Initial approval is for three months
Continued therapy

- Patient continues to meet initial approval criteria
- Prescriber attestation of patient compliance with doses and treatment visits
- Attestation or documentation of clinical improvement as evidenced by improvement in the same validated rating scale used for baseline depression assessment
- Documentation of concurrent use of antidepressant

Reauthorization is for 12 months

REMS

Spravato is available through a Risk Evaluation and Mitigation Strategy (REMS) program to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and abuse and misuse of Spravato by ensuring that:

- Spravato is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients.
- Ensuring pharmacies and healthcare settings that dispense Spravato are certified.
- Each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring.
- All patients who receive treatment are enrolled in an outpatient healthcare setting in a registry to further characterize the risks and support safe use.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code S0013 (esketamine, nasal spray, 1 mg)

Prescribing Restrictions

Frequency of billing = 84 mg / 84 units twice weekly
Maximum billing unit(s) = 84 mg/ 84 units
Formoterol Fumarate
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.

Ganciclovir Long-Acting Implant
The ganciclovir, 4.5 mg, long-acting implant is billed with HCPCS code J7310 for the treatment of cytomegalovirus (CMV) retinitis in patients with AIDS.

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.

Billing
The ganciclovir long-acting implant is reimbursable when billed in conjunction with ICD-10-CM diagnosis codes B25.8, B25.9 (cytomegaloviral disease) or codes H30.001 through H31.099 (chorioretinal inflammation and other disorders of choroid). The implantation procedure is billed using CPT® 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 patient 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:

- The patient 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 patient 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)/Additional Claim Information 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.
**Goserelin**
Goserelin is reimbursable for the treatment of endometriosis, advanced carcinoma of the prostate and for the palliative use in women with advanced breast cancer.

**Dosage**
The maximum dosage is 10.8 mg every 28 days.

**Billing**
HCPCS code J9202 (goserelin acetate implant, per 3.6 mg)

**Granisetron (Oral Tablets)**
Granisetron hydrochloride is indicated for the prevention of:

- 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 Implant**

HCPCS code J9225 (histrelin implant, 50 mg, Vantas®), for the treatment of males 30 years of age or older with prostate cancer, is reimbursable when billed with ICD-10-CM diagnosis code C61. Coverage is limited to one in 12 months.

HCPCS code J9226 (histrelin implant, 50 mg, Supprelin LA®), is used for the treatment of precocious puberty in children aged 2 through 15 years. Claims may be reimbursed when billed in conjunction with ICD-10-CM diagnosis code E30.1 or E30.8. Coverage is limited to one in 12 months.

**Lidocaine and Tetracaine Patch**

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

**Rolapitant**

Rolapitant is a substance P/neurokinin 1 (NK1) receptor antagonist indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
Dosage
The recommended dosage is 180 mg rolapitant administered approximately one to two hours prior to the start of chemotherapy in patients 18 years of age and older. Administer dosage in combination with dexamethasone and a 5-hydroxytryptamine3 (5-HT3) receptor antagonist.

Required Code
ICD-10-CM diagnosis code R11.2

Billing
HCPCS code J8670 (rolapitant, oral, 1 mg)

Testosterone Pellet
HCPCS code S0189 (testosterone pellet, 75 mg), 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-10-CM diagnosis codes E29.1, E29.8 or E29.9.

Dosage
Maximum dosage is 450 mg every 90 days.

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 the American Association for the Study of Liver Diseases (AASLD)/ Infectious Diseases Society of America (IDSA). This policy may be revised as new information becomes available. This policy may be revised as new information becomes available.

Treatment Considerations and Choice of Regimen for Hepatitis C Virus (HCV) Infected Patients
Please refer to AASLD guidelines for recommended treatment regimens and durations.
Identifying Treatment Candidates

a. Treatment is recommended for all patients with chronic HCV infection, except those with a short life expectancy who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.

b. Patient readiness and adherence:
   i. Patients shall be evaluated for readiness to initiate treatment.
   ii. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
   iii. Caution shall be exercised with patients who have a history of treatment failure with prior HCV treatment due to non-adherence with treatment regimen and appointments.
   iv. Patients shall be educated regarding the potential risks and benefits of HCV therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.

Other considerations

Quantity limits:
   i. Prescription of HCV therapy will be dispensed in quantities up to 28 days at a time.

Criteria for reauthorization/continuation of therapy:
   i. Initial authorization criteria have been met.
   ii. Evidence of lack of adherence may result in denial of treatment reauthorization.
   iii. Missed medical appointments related to HCV may result in the denial of treatment authorization.

Labaratory testing:
   i. Documentation of baseline HCV-RNA level.
   ii. Laboratory testing and monitoring should be consistent with current AASLD/IDSA guidelines.
Populations Unlikely to Benefit from HCV Treatment

According to AASLD/IDSA HCV guidelines, “Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation or another directed therapy do not require antiviral treatment. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.” Please refer to AASLD guidelines for more information on populations unlikely to benefit from HCV treatment (hcvguidelines.org).

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
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:

- Reference to current medical literature.
- Consultation with provider organizations, academic and professional specialists.

Age Requirements
As approved by FDA.

Quantity Limits
Up to 28 days at a time.
Legend

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