

BILLING INFORMATION



A path
forward
in ALL

Clolar is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia (ALL) after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted.

Clolar[®]
clofarabine injection



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clofarabine injection

This guide is intended solely for use as a tool to assist hospital inpatient and outpatient billing staff regarding reimbursement issues. Any determination about whether and how to seek reimbursement should be made solely by the appropriate members of the hospital or billing staff in consultation with the physician and in light of the procedure performed on a particular patient. Genzyme Corporation does not recommend or endorse the use of any particular procedure code(s) and makes no determination whether or how reimbursement may be available. Also, it is important to note that reimbursement codes and procedures can change. This information is believed to be current as of February 23, 2009.

Spot Glue PI

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Introduction

Clolar® is a purine nucleoside anti-metabolite analogue; older agents in this drug class include fludarabine and cladribine.

Indication

Clolar was approved by the U.S. Food and Drug Administration (FDA) in December 2004 for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted.

Please see full prescribing information.

Dosing

Clolar is administered by intravenous (I.V.) infusion daily for five consecutive days. Each treatment will take approximately two hours. Treatment cycles are repeated following recovery or return to baseline organ function, approximately every 2 to 6 weeks.

About this Guide

This billing guide is intended to provide the most current available information about coding, reimbursement, and coverage of Clolar in 2009. Throughout this guide, we highlight coverage and reimbursement under the Medicare program because many payers follow Medicare's lead for billing and coding practices. The guide reviews the claims submission process and provides sample claim forms to use when billing for Clolar in the hospital inpatient and hospital outpatient settings. In addition, the guide assists providers in documenting medical necessity and explains reimbursement support programs for patients. Given the pediatric indication for Clolar, private insurers and Medicaid will likely be major payers for patients receiving Clolar therapy.

Important Safety Information About Clolar

Adverse Reactions

- Most common adverse reactions with Clolar were nausea (73%), vomiting (78%), diarrhea (56%), febrile neutropenia (55%), headache (43%), rash (38%), pruritus (43%), pyrexia (39%), fatigue (34%), palmar-plantar erythrodysesthesia syndrome (16%), anxiety (21%), flushing (19%), and mucosal inflammation (16%).

Precautions and Warnings:

- Clolar should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy.

Hematologic Toxicity

- Monitor complete blood counts and platelet counts during Clolar therapy.
- Suppression of bone marrow function should be anticipated. This is usually reversible and appears to be dose dependent. Severe bone marrow suppression, including neutropenia, anemia, and thrombocytopenia, has been observed in patients treated with Clolar. At initiation of treatment, most patients in the clinical studies had hematological impairment as a manifestation of leukemia.
- Because of the pre-existing immunocompromised condition of these patients and prolonged neutropenia that can result from treatment with Clolar, patients are at increased risk for severe opportunistic infections.

Infections

- The use of Clolar is likely to increase the risk of infection, including severe sepsis, as a result of bone marrow suppression. Monitor patients for signs and symptoms of infection and treat promptly.

Hyperuricemia (Tumor Lysis)

- Administration of Clolar may result in a rapid reduction in peripheral leukemia cells. Evaluate and monitor patients undergoing treatment for signs and symptoms of tumor lysis syndrome. Provide intravenous infusion fluids throughout the five days of Clolar administration to reduce the effects of tumor lysis and other adverse events. Administer Allopurinol if hyperuricemia (tumor lysis) is expected.

Systemic Inflammatory Response Syndrome (SIRS) or Capillary Leak Syndrome

- Evaluate and monitor patients undergoing treatment with Clolar for signs and symptoms of cytokine release (e.g., tachypnea, tachycardia, hypotension, pulmonary edema) that could develop into systemic inflammatory response syndrome (SIRS), capillary leak syndrome and organ dysfunction.
- Discontinue Clolar immediately in the event of clinically significant signs or symptoms of SIRS or capillary leak syndrome, either of which can be fatal, and consider use of steroids, diuretics, and albumin. Re-institute Clolar when the patient is stable, generally with a 25% dose reduction. The use of prophylactic steroids may be of benefit in preventing signs and symptoms of cytokine release.

Hepatic Enzymes

- Hepato-biliary enzyme elevations were frequently observed in pediatric patients during treatment with Clolar. Some patients discontinued treatment due to hepatic enzyme abnormalities.

Hepatic and Renal Impairment

- Clolar has not been studied in patients with hepatic or renal dysfunction. Its use in such patients should be undertaken only with the greatest caution.
- Patients who have previously received a hematopoietic stem cell transplant (HSCT) may be at higher risk for hepatotoxicity suggestive of veno-occlusive disease (VOD) following treatment with clofarabine (40 mg/m²) when used in combination with etoposide (100 mg/m²) and cyclophosphamide (440 mg/m²). Severe hepatotoxic events have been reported in an ongoing Phase 1/2 combination study of clofarabine in pediatric patients with relapsed or refractory acute leukemia.

Use in Pregnancy

- Clolar can cause fetal harm when administered to a pregnant woman. Intravenous doses of clofarabine in rats and rabbits administered during organogenesis caused an increase in resorptions, malformations, and variations. Women of childbearing potential should be advised to avoid becoming pregnant while receiving Clolar.

Nursing Mothers

- Female patients should be advised to avoid breast-feeding during treatment with Clolar.

Incidence of Treatment Emergent Laboratory Abnormalities

- Grade 3 or higher myelosuppression: anemia (75%), leukopenia (88%), lymphopenia (82%), neutropenia (64%), and thrombocytopenia (80%).
- Grade 3 or higher renal and liver abnormalities: elevated creatinine (8%), elevated SGOT (36%), elevated SGPT (43%), and elevated total bilirubin (13%).

Coverage

Payers generally cover medically necessary drug therapies that meet the following criteria:

- The therapy is used according to the labeled indications approved by the FDA, and/or
- The therapy is listed in the major drug compendia

Medicare¹

Medicare may make coverage decisions for Clolar at a local level through Medicare contractors known as fiscal intermediaries (FIs), carriers, and Medicare Administrative Contractors (MACs). These decisions, referred to as local coverage determinations (LCDs), apply only to the contractor's jurisdiction. Therefore, the specific criteria as to which patients qualify for coverage and what documentation is required may vary by local Medicare contractor and will evolve continuously. As of January 2009, there was no national coverage determination (NCD) for Clolar. However, at its discretion, Medicare could provide coverage guidance at the national level through a lengthy, open process that culminates in a national coverage determination.

Check with your local Medicare contractor to determine whether any local coverage policies apply to Clolar.

Medicaid

Medicaid programs generally cover drugs for their FDA approved indications; however, Medicaid coverage policies are determined on a state-by-state basis. While some state Medicaid programs may utilize coverage guidelines for Clolar that mirror Medicare's policies, other programs may provide more limited benefits. In addition, some state programs may have prior authorization (PA) requirements for Clolar.

For specific information regarding Clolar, check with your state's Medicaid program.

Private Payers

Most private payers cover drug therapies when determined to be medically necessary and appropriate; however, benefits vary from payer to payer and also depend on the specific contract terms that a provider negotiates with a given plan. Some private insurers have medical criteria for coverage similar to those used by Medicare, while others have developed their own policies. As a condition of coverage, some managed care plans also may require that providers obtain prior authorization before covering Clolar therapy.

Check your patient's policy to determine the specific policy limits or requirements that might apply to Clolar.

1. Through Medicare contractor reform, over time carriers and FIs are expected to be replaced by Medicare Administrative Contractors (MACs). MACs will process claims for both the hospital and community setting.

Hospital Inpatient Setting

Medicare

Medicare and some private insurers reimburse hospitals for inpatient care using diagnosis-related groups (DRG). In fiscal year (FY) 2008, Medicare replaced the existing DRG system with Medicare Severity diagnosis-related groups (MS-DRGs). The MS-DRGs are assigned based on a patient's principal and secondary diagnoses, the procedures performed during an inpatient stay, and the severity of the patient's illness. The MS-DRG system is designed to provide more accurate payment to hospitals and provide financial incentive to more thoroughly assess and respond to patient medical needs. A list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes relevant to Clolar appears in Appendix A. Each MS-DRG corresponds to a fixed, pre-determined payment amount to a hospital, regardless of the actual resources used². In some cases, allowances for outlier cases can affect the total payment that a hospital will receive. For this reason, thorough and accurate coding and reporting of charges is essential to ensure appropriate payment for all hospital resources. MS-DRG payments to hospitals are intended to cover all facility costs for an inpatient hospital stay, excluding payments for physicians' professional services. Additionally, MS-DRG payments to hospitals are required to include the costs of related hospital outpatient services performed within three days prior to admission.

Medicaid

Each state Medicaid program determines its own payment methodology for hospital inpatient services. The majority of states reimburse for hospital inpatient services using prospective payment systems, which include DRGs and per-diem rates, as explained above, and may provide a single payment to the hospital with no separate payment for Clolar therapy or other services. However, some state Medicaid programs use other reimbursement methods including cost-based payments. Many Medicaid programs also adjust payments to reflect a hospital's case mix or the intensity of care required by patients treated at the facility.

Private Payers

Most private payers pay hospitals for inpatient care based on case-rates or per-diems. Other less common payment arrangements used by private payers include a modified form of the Medicare diagnosis-related group (DRG) system, percentage of allowable charges, and negotiated rates for particular treatments. Most private insurers negotiate contracts with facilities regarding hospital inpatient payment methods. These contracts typically are negotiated annually or every couple of years. Case-rates are pre-determined payment amounts that are set according to the type of diagnoses assigned or procedures performed. Case-rates can be inclusive of all drugs and services provided for the inpatient stay. Unlike DRGs, however, case-rates may bundle hospital and physician payments together. Per-diem rates are a negotiated prospective payment for each day of care, regardless of the resources used. Per-diem rates vary within geographic markets and are plan specific. Payers can use a single per-diem to pay for all types of patient services provided, or they may use different per-diem rates to reflect different types of services, such as surgical and medical services. Payment for Clolar likely will be included in the case-rate payment set under the contractual agreement between the payer and hospital. Under some contracts, hospitals may receive additional separate payment for Clolar (carve outs) in addition to the case-rate as a new technology until the contract is renewed and renegotiated.

² Actual MS-DRG payments will vary by hospital to reflect a number of hospital-specific and geographic adjustment factors.

The following MS-DRGs may be relevant for Clolar therapy:

| MS-DRG | Description |
|--------|--|
| 837 | Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with Major CC |
| 838 | Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent |
| 839 | Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC |

The table below lists fiscal year (FY) 2009 national average payment amounts by hospital type for MS-DRG 837, 838, and 839. However, actual payment will vary based on a number of factors such as geographic region and hospital type (urban, teaching).

| Hospitals | FY 2009 National Average Payment Amount for MS-DRG 837 | FY 2009 National Average Payment Amount for MS-DRG 838 | FY 2009 National Average Payment Amount for MS-DRG 839 |
|--------------|--|--|--|
| Base Payment | \$32,681 | \$15,085 | \$7,251 |

Some inpatient cases may qualify for an additional Medicare outlier payment. A case qualifies as an outlier if the total costs (as opposed to charges) for the case exceed the MS-DRG payment by more than \$20,045, according to the Medicare Hospital Inpatient Prospective Payment System (PPS) final rule for fiscal year 2009. For example, the national average payment estimate for MS-DRG 837 is \$32,681. For this MS-DRG, an outlier payment will kick in when the total facility costs for each MS-DRG exceed \$52,726 (\$32,681 + \$20,045).

Once the cost exceeds this amount, Medicare will pay 80 percent of the amount in excess of each threshold, plus the entire MS-DRG payment. For example, if total costs for a MS-DRG 837 case are \$53,726, Medicare would be expected to pay the MS-DRG payment plus \$800 (.80 x \$1,000).

In essence, in order to qualify for an outlier payment, a hospital must incur a loss of \$20,045 beyond the MS-DRG payment. Once it qualifies, the hospital is eligible to receive 80% of additional costs.

Outlier payments can vary depending on many factors—not only will the MS-DRG payment amounts be different for each hospital, but the total costs for an inpatient stay will vary on a case-by-case basis.

The Centers for Medicare and Medicaid Services (CMS) explicitly excludes some designated cancer hospitals and children’s hospitals from the inpatient prospective payment system. These DRG-exempt facilities are paid based on costs or under their own prospective payment systems (see Appendix B for the list of MS-DRG-exempt facilities).

| | | |
|----------------------|--|-----------------------|
| Total Costs | Remaining Costs (adjusted from charges) | Medicare Pays: 80% |
| Fixed-loss Threshold | Fixed Loss: \$20,045 | 0% |
| | MS-DRG Payment | 100% |

Hospital Outpatient Setting

Coding for Services in the Hospital Outpatient Setting

Patients may receive chemotherapy in the hospital outpatient department (HOPD). Correctly identifying the treatment setting is critical because Medicare coding and reimbursement for physician-administered drugs, such as Clolar, depends upon the setting in which the drug therapy is administered.

The facility and the physician will submit a separate claim for Clolar when it is infused in an HOPD. The HOPD must submit a properly coded CMS-1450 (UB-04) claim form to obtain reimbursement for facility costs including the drug. The physician must submit a properly coded CMS-1500 claim form for professional services rendered.

Both types of claims must include codes for

- The patient's diagnosis
- The procedures performed

The hospital CMS-1450 (UB-04) claim also must include a code for

- The drug being used for treatment

You will find sample codes for billing Clolar below. In addition, sample CMS-1450 (UB-04) claim forms are included later in this guide (see pages 20-21).

Diagnosis Codes

All claim forms must include at least one ICD-9-CM diagnosis code. The diagnosis codes that may apply to patients treated with Clolar for the diagnosis and/or treatment of acute leukemias are included later in this guide under Appendix A. If these diagnosis codes do not apply to your patient, please indicate the appropriate diagnosis codes on the claim form.

Providers should select the most appropriate codes with the highest level of detail to describe a patient's condition. Your local FI carrier, or MAC may require specific information to be included on or with the CMS-1450 (UB-04) and CMS-1500 claim forms.

Drug Codes

The hospital will purchase Clolar and bill for the drug using a Healthcare Common Procedure Coding System (HCPCS) code. Effective January 1, 2006, CMS assigned Clolar its own HCPCS J code, J9027, Injection, clofarabine, 1 mg. Therefore, Clolar may be billed to all payers using this J code. However, providers should check with private payers to verify appropriate coding for Clolar.

| HCPCS Code | Description |
|------------|------------------------------|
| J9027 | Injection, clofarabine, 1 mg |

Procedure Codes

In addition to the diagnosis code, the physician and HOPD may submit the appropriate Current Procedural Terminology (CPT)³ code to bill for the procedures involved in administering Clolar. However, please check with your payer to confirm what codes should be used for the administration of Clolar. Providers may find the following codes appropriate for this procedure when billing private payers, Medicaid and Medicare:

| CPT Code | Modifier Description |
|----------|---|
| 96413 | Chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug |
| 96415 | Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) |

CPT Code Modifiers

It may be appropriate to separately bill each procedure the physician performs. Where necessary, the CPT system includes two-digit modifiers to define services in addition to the primary procedure. The following modifier may be relevant for Clolar therapy:

| Modifier | Modifier Description |
|----------|-----------------------------|
| -59 | Distinct procedural service |

Revenue Codes

The National Uniform Billing Committee, overseen by the American Hospital Association, developed a detailed set of accounting codes to standardize major institutional setting revenue-producing centers. These codes identify categories of service like supplies, oncology, pharmacy, and laboratory. Hospitals use these codes to group charges for hospital services. Revenue codes appear on CMS-1450 (UB-04) claim forms and are processed by most insurers. The following revenue codes may be relevant for Clolar therapy:

| Revenue Codes | Modifier Description |
|---------------|--|
| 0250 | General pharmacy |
| 0636 | Drugs requiring HCPCS codes/detailed coding (for HOPD) |
| 0260 | I.V. therapy |
| 0280 | Oncology |
| 0335 | Chemotherapy I.V. |

3. Current Procedural Terminology (CPT)(c). American Medical Association. All rights reserved.

Reimbursement in the Hospital Outpatient Setting

Reimbursement for Clolar will vary by insurer and setting. Most patients share in the cost of their medical care through coinsurance, deductibles, or copayments. For services performed in the HOPD, there will usually be two claims submitted, a CMS-1500 claim form for the physician services performed and a CMS-1450 (UB-04) claim form for the hospital's facility costs. The patient will have some financial responsibility for both the physician services and the hospital charges.

Medicare Reimbursement for Facility Costs in the HOPD

Medicare pays the HOPD for services based on the ambulatory payment classification (APC) system, also known as the Medicare Hospital Outpatient Prospective Payment System (OPPS). Each APC is associated with a fixed payment amount that will be paid regardless of the hospital's cost. Each APC also has a fixed patient coinsurance portion that may exceed 20 percent of the total charges. The procedure APC payment and coinsurance are adjusted for geographic wage differences.

| CPT Code | Descriptor | APC | Status Indicator | 2009 Payment Rate | 2009 National Unadjusted Copay | 2009 Minimum Unadjusted Copay |
|----------|---|-----|------------------|-------------------|--------------------------------|-------------------------------|
| 96413 | Chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug | 440 | S | \$187.96 | N/A | \$37.60 |
| 96415 | Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) | 437 | S | \$36.13 | N/A | \$7.23 |

Reimbursement rates for CPT codes 96413 and 96415 in the HOPD for 2009 are provided below. Status Indicator S – significant procedure, not discounted when multiple.

CMS excludes some hospitals from reimbursement under APCs. Excluded facilities currently include designated critical access hospitals (CAHs), Maryland hospitals subject to the state's cost containment program, and Indian Health Service hospitals.

Medicare Reimbursement for Drugs in the HOPD

Clolar is classified as a non-pass through drug and biological separately paid under OPPS. For FY 2009, payment for Clolar as well as most other separately payable drugs and biologicals is set at 104 percent of its average sales price (ASP). The APC payment rate for Clolar in the table below, is from the January 2009 update to Addendum B of the calendar year (CY) 2009 OPPS Final Rule, released by CMS. The reimbursement rate is likely to change slightly during each quarter of 2009. Please call 800-RX-CLOLAR for the most current reimbursement amount for Clolar.

| HCCPS Code | Description | APC | OPPS National Payment Rate |
|------------|------------------------------|------|----------------------------|
| J9027 | Injection, clofarabine, 1 mg | 1710 | \$114.41 |

Private Payers

Private payers may pay for Clolar based on a percentage of billed or allowable charges, negotiated payment rates, or preset per-diem rates. The exact payment mechanism used by a specific payer usually depends on the hospital's contractual agreement with that payer. See the Medicare section above because most payers follow Medicare's lead for billing and coding.

Medicaid

Medicaid programs may pay for Clolar therapy based on state-specific fee schedules, preset per-diem/per-visit rates, or percentage of charges. There is significant variation in Medicaid payment amounts among states. Please check with your state Medicaid agency for payment information in your area.

Documenting Medical Necessity and Appealing Denied Claims

Proper coding is the first step in obtaining correct reimbursement for Clolar and the services related to its administration. Because of the nature of prospective payment systems like Medicare's MS-DRG system, which provides bundled payment to hospitals, claims problems in these payment systems are more often due to the submission of incorrect codes than to outright claims denials. In other systems, like Medicare's APC system, which pays for many drugs on a line-item basis, if you receive a denied claim for Clolar, you may be able to successfully appeal the denial if the treatment was medically necessary and given for the appropriate indication. The following information may serve as a resource regarding responding to denied claims.

Review the Denial

Review the explanation of benefits (EOB) sent by the insurer. Claims are most commonly denied due to administrative errors such as missing identification numbers, patient names, or signatures. Claims also may be denied for missing or improper codes or modifiers. After correcting any errors you identify, you may decide to resubmit the claim.

Resubmit the Claim with More Information

If you determine that the denial was not a result of claim submission errors, you may consider submitting materials that document medical necessity, such as a letter of medical necessity that highlights the following:

- The patient's medical history
- Other therapies that have been tried or were contraindicated
- The reasons Clolar was prescribed for this particular patient
- The risks of foregoing Clolar treatment

For your convenience, we have included a sample letter of medical necessity at the back of this billing guide (Appendix C). In addition, you may wish to include the following information with a resubmitted claim:

- Clolar package insert
- Peer-reviewed clinical articles on Clolar
- Copies of favorable coverage policies for Clolar

Appeal the Denial

If a claim is denied a second time, you may wish to contact the claims manager or the medical director of the insurer to request a hearing or to file a grievance. Providers should be prepared to submit copies of claims and supporting documentation.

Patients or their representatives may decide to get involved. Patients with employer-sponsored coverage can begin their advocacy through their human resources or benefits offices. Patients insured by traditional Medicare may contact their local Medicare claims processor to inquire about their appeal rights. Patients enrolled in a Medicare Advantage⁴ plan may contact the consumer affairs hotline at their plan to ask for reconsideration. Patients covered by Medicaid may contact the state program office to obtain information on appeals.

Reimbursement Assistance

CLOLAR Direct

Clolar patients and those who care for them have direct access to comprehensive support services, including assistance with reimbursement questions, from Genzyme. This support program provides a one-stop information resource for reimbursement and patient access questions.

Staffed with specialists with expertise in public and private health insurance, the program offers assistance in the following ways:

- Clarify public and private coverage requirements for Clolar
- Provide coding information for billing Clolar
- Verify primary, secondary, and tertiary patient benefits
- Identify opportunities for coverage advocacy
- Screen patients for the patient assistance program

Call 800-RX-CLOLAR (800-792-5652) Monday through Friday from 9:00 a.m. to 5:00 p.m. ET. Or visit www.clolar.com for more information.

Glossary of Reimbursement Terms

Ambulatory payment classification (APC) system—System developed and maintained by CMS for the payment of hospital outpatient services. The total payment and patient coinsurance amounts for each group are predetermined.

Average sales price (ASP)—A reference point for reimbursement of drugs and biologicals. The manufacturer's total sales—excluding sales that are exempt from the Medicaid best price calculation and sales to an entity that are nominal in amount, and including prompt pay discounts, cash discounts, free goods, and rebates—to all purchasers in the United States for the national drug code (NDC) for a quarter divided by the total number of units of that NDC sold by the manufacturer in that quarter.

Centers for Medicare and Medicaid Services (CMS)—The federal agency that oversees Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

Coinsurance—A type of cost-sharing arrangement under which the patient pays a percentage of each unit of service, with the insurer paying the remaining percentage. For example, Medicare pays 80 percent of the allowable amount for Part B services, and the patient is responsible for the coinsurance of 20 percent.

Copayment—A type of cost-sharing arrangement under which the patient pays a fixed dollar amount per unit of service.

Current Procedural Terminology (CPT)—A set of five-digit codes published by the American Medical Association to represent medical services. They are also referred to as Level I HCPCS codes.

Deductible—The fixed dollar amount that the patient must pay for care before any insurance payment is made.

Diagnosis-Related Group (DRG)—A system for determining hospital inpatient reimbursement based on the patient's diagnoses and procedures performed during stay; used by some Medicaid programs and private insurers. See also Medicare Severity Diagnosis-Related Groups.



Explanation of Benefits (EOB)—Also called an explanation of medical benefits (EOMB). This is a statement sent to the insured from the insurer listing the services provided, the amount billed, and the payment made. If a service is denied, the EOB should list the reason for the denial.

Healthcare Common Procedure Coding System (HCPCS)—CMS-assigned billing codes for services and supplies not represented by a CPT code. Use of these codes is mandatory for Medicare and Medicaid billing.

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)—A system of four- or five-digit codes describing diagnoses and procedures. ICD-9-CM is managed by CMS, The Centers for Disease Control and Prevention (CDC), and the National Center for Health Statistics (NCHS) with input from the American Medical Association (AMA) and the private insurance industry.

Medicaid—A joint federal and state program providing health care coverage to low-income families and persons with disabilities, as well as long-term care to low-income elderly.

Medicare—A federally-funded program that provides health insurance benefits to the elderly, persons with disabilities, and patients with end-stage renal disease.

Medicare Advantage Plan—Private insurance plans offered to Medicare beneficiaries under a contract with CMS. For patients who enroll in these plans, claims processing decisions are made by the private plan.

Medicare Carrier—A private company that contracts with CMS to process Medicare Part B claims.

Medicare Severity Diagnosis Related Group (MS-DRG) —A system used by Medicare for determining hospital inpatient reimbursement based on the patient's diagnosis, procedures performed during the stay, and severity of illness. The MS-DRG system replaces the historical DRG system used by Medicare.

Modifier—This is normally a two-digit numeric or alpha-numeric code that denotes a change in the CPT or HCPCS code with which it is used. For example, modifier -50 denotes that the procedure being billed was performed bilaterally.

Prior Authorization (PA)—Also known as preauthorization or precertification. This involves obtaining advance approval from an insurer to perform the requested services.

Private Payers—An organization (insurance company) that pays for health or medical expenses on behalf of beneficiaries or recipients. The individual usually pays a premium for such coverage.

U.S. Food and Drug Administration (FDA)—The federal agency that regulates pharmaceuticals, biologicals, and medical devices.

Wholesale Acquisition Cost (WAC)—The list price for wholesalers, distributors, and other direct accounts before any rebates, discounts, allowances, or other price concessions that might be offered by the supplier of the product.

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APPENDICES

Appendix A: ICD-9-CM Diagnosis Codes

| ICD-9-CM Codes | Description |
|----------------|---|
| V58.11 | Encounter for antineoplastic chemotherapy |
| 204.0Y | Lymphoid leukemia, acute |
| 204.1Y | Lymphoid leukemia, chronic |
| 204.2Y | Lymphoid leukemia, subacute |
| 204.8Y | Lymphoid leukemia, other |
| 204.9Y | Lymphoid leukemia, unspecified |

NOTE: Y=0: Without mention of remission; Y=1: In remission; or Y=2: In relapse

Appendix B: List of DRG-Exempt Facilities⁵

| Name | City and State |
|--|------------------|
| City of Hope National Medical Center | Duarte, CA |
| USC Kenneth Norris Jr. Cancer Hospital | Los Angeles, CA |
| University of Miami Hospital and Clinics | Miami, FL |
| Dana-Farber Cancer Institute | Boston, MA |
| Memorial Sloan-Kettering | New York, NY |
| Roswell Park Memorial Institute | Buffalo, NY |
| Arthur G. James Cancer Hospital and Research Institute | Columbus, OH |
| American Oncologic Hospital (Fox Chase) | Philadelphia, PA |
| The University of Texas M.D. Anderson Cancer Center | Houston, TX |
| Fred Hutchinson Cancer Research Center | Seattle, WA |
| H. Lee Moffitt Cancer Center | Tampa, FL |

5. Centers for Medicare and Medicaid Services. Medicare PPS Excluded Cancer Hospitals http://www.cms.hhs.gov/AcuteInpatientPPS/10_PPS_Exc_Cancer_Hosp.asp (Last modified on December 14, 2005).

Appendix C: Sample Letter of Medical Necessity

[Date]

[Name of Medical Director]

[Name of Insurer]

[Address]

[City, State, Zip Code]

Re: [Patient Name]
[Patient I.D. Number]

Dear Dr. [Name of Medical Director]:

I am writing to provide additional information for the enclosed claim for medical services provided to [insert patient's name and I.D. number]. This patient required Clolar® (clofarabine injection) therapy as a result of [insert medical diagnosis]. Clolar is a purine nucleoside analog which inhibits DNA production necessary for cancer cell growth. Clolar is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted. Clolar was approved by the U.S. Food and Drug Administration (FDA) on December 28, 2004.

This letter provides information on the patient's medical history and treatment, Clolar administration procedure, and the reasons why it was medically necessary and appropriate for this patient.

[Insert patient's case history, including the patient's condition and clinical course prior to administration of Clolar and the treatment rationale (why this product and procedure were chosen for this particular patient)].

[Insert Clolar administration procedure description with specific reference to its advantages.]

I hope that this letter has been helpful in explaining the advantages and clinical benefits of Clolar therapy and its value for this patient. The Clolar therapy was medically necessary in this case based on the information I have just presented. Accordingly, the claim should be approved for payment.

Please call me at [insert phone number] if you require any additional information.

Sincerely,

[Physician's name]

Appendix D: Sample Letter of Appeal for a Denied Claim

[Date]

[Name of Medical Director]

[Insurer Name]

[Address]

[City, State, Zip Code]

Re: [Patient Name]
[Patient I.D. Number]
[Claim Number]

Dear Dr. [Name of Medical Director]:

I am writing to appeal formally a denied claim for services provided to [insert patient's name, I.D. number, and claim number]. Based on a clinical assessment of my patient, the patient's diagnosis, and medical history, Clolar® (clofarabine injection) therapy was medically necessary. This letter provides my clinical rationale for Clolar therapy. It presents information about this patient's medical condition, discusses Clolar indications and the administration procedure, and explains why it was medically necessary and appropriate for this patient.

Clolar is a purine nucleoside analog which inhibits DNA production necessary for cancer cell growth. Clolar is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted. Clolar was approved by the U.S. Food and Drug Administration (FDA) on December 28, 2004.

[Insert patient's case history, including the patient's condition and clinical course prior to Clolar therapy.]

[Insert Clolar administration procedure with specific reference to pre-operative advantages of this therapy for certain high-risk cases.]

Based on the clinical evidence for this case, Clolar therapy was medically necessary. Accordingly, this claim should have been approved for payment.

I hope that this letter has been helpful in explaining the necessity and value of Clolar therapy for this patient. I have enclosed the following documents to assist you in your reconsideration of this claim:

- a copy of the denied claim;
- clinical literature on Clolar therapy and the clinical benefits; and
- [any additional relevant information to support the appeal, such as medical notes].

Thank you for your reconsideration of coverage for this patient's treatment. Please call me at [insert phone number] if additional information is required.

Sincerely,

[Physician's name]

Appendix E: Sample CMS-1450 (UB-04) Paper Claim Form for Inpatient Services

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| 1 Anytown ICF/DD 1 Maple Avenue Anytown, NY 11111 | | 2 | | 3a PAT CONTL # AB1234567 | | 4 TYPE OF BILL 0111 | |
| 6 PATIENT NAME Smith, William | | 9 PATIENT ADDRESS 121 Main Street Anytown, NY 11111 | | | | | |
| 10 BIRTHDATE MMDDYY M | | 11 SEX | | 12 DATE | | 13 ADMISSION DATE | |
| 14 OCCURRENCE CODE | | 15 OCCURRENCE DATE | | 16 OCCURRENCE CODE | | 17 OCCURRENCE DATE | |
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Appendix F: Sample CMS-1450 (UB-04) Paper Claim Form for Outpatient Services

| | | | | | | | |
|--|---------------------------------|---|--------------|---|------------------|----------------------------|----|
| 1 Anytown ICF/DD 1 Maple Avenue Anytown, NY 11111 | | 3 | | 50 PAT ONTL # AB1234567 | | 4 TYPE OF BILL 0131 | |
| 8 PATIENT NAME Smith, William | | 9 PATIENT ADDRESS 121 Main Street Anytown, NY 11111 | | | | | |
| 10 BIRTHDATE | | 11 SEX | | 12 DATE | | 13 ADMISSION | |
| 14 MMDDYY | | 15 OCCURRENCE DATE | | 16 OCCURRENCE DATE | | 17 OCCURRENCE DATE | |
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| This document is provided for your guidance only. Please call the Clolar Direct Program at 800-RX-CLOLAR (800-792-5652) to verify coding and claim information for specific payers. | | | | | | | |
| 42 REV CD | 43 DESCRIPTION | 44 HCPCS / RATE / HPPS CODE | 45 SERV DATE | 46 SERV UNITS | 47 TOTAL CHARGES | 48 NON-COPIED CHARGES | 49 |
| 0636 | Drugs requiring detailed coding | J9027 | MMDD09 | 40 | XXX XX | | |
| 0335 | Chemotherapy, I.V. infusion | 96413 | MMDD09 | 1 | XXX XX | | |
| 0335 | Chemotherapy, I.V. infusion | 96415 | MMDD09 | 1 | XXX XX | | |
| Field 42 Revenue Code and Field 43 Description: Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44. Examples: - 0636 used for Clolar - 0335 used for the I.V. infusion of Clolar | | Field 44 HCPCS/Rate/HPPS Code: Enter appropriate Product and service codes. Examples: - Drug HCPCS code J9027 Injection, clofarabine, 1 mg - Administration CPT codes 96413 Chemotherapy administration, I.V. infusion technique; up to 1 hour, single or initial substance/drug 96415 Chemotherapy administration, I.V. infusion technique; each additional hour (Use this code if the duration of the I.V. infusion is at least 91 minutes) | | Field 46 Service Units: Enter appropriate number of service units. Example: - Clolar J9027 (per 1 mg) 40 mg is reported with 40 billing units. | | | |
| PAGE OF | | CREATION DATE | | TOTALS | | | |
| 53 PAYER NAME Medicare | | 54 HEALTH PLAN ID | | 55 EST AMOUNT DUE | | 56 MFY | |
| 57 OTHER PRTY ID | | 58 INCL | | 59 ED'S UNIQUE ID | | 60 INSURANCE GROUP NO. | |
| 61 GROUP NAME | | 62 EMPLOYER NAME | | 63 TREAT | | 64 DOCUMENT CONTROL NUMBER | |
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| 29 | | 30 | | 31 | | 32 | |
| 33 | | 34 | | 35 | | 36 | |
| 37 | | 38 | | 39 | | 40 | |
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Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

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