BILLING AND CODING INFORMATION FOR HOSPITAL OUTPATIENT

Pfizer Oncology together™

MYLOTARG™ (gemtuzumab ozogamicin) is indicated for the treatment of newly diagnosed CD33-positive acute myeloid leukemia (AML) in adults, and relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older.

The table below provides a brief overview of relevant billing and coding information for MYLOTARG, presented in greater detail with the sample UB-04/CMS-1450 form on the next page.

Item	Revenue code	Additional coding (HCPCS, ICD-10-CM, and CPT®)	Considerations
Drug: MYLOTARG (gemtuzumab ozogamicin)[1-3] **(HCPCS)**	Include the appropriate revenue code for each line item based on hospital billing policy, e.g.: **Medicare:** • 0636 - Drugs Requiring Detailed Coding **Other payers:** • 0250 - General Pharmacy OR • 0260 - General Classification (IV Therapy) OR • 0280 - General Classification (Oncology) OR • 0636 - Drugs Requiring Detailed Coding (if required by payer)	**Medicaid, Medicare, and commercial payers:** • J9203 - Injection, gemtuzumab ozogamicin, 0.1 mg Notes: Medicare requires the use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers' requirements for documenting discarded drug amount, including use of the JW modifier, may vary. Most 340B hospitals must report J9203 with the TB modifier (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) on Medicare claims when MYLOTARG is purchased through the 340B program. For more information on 340B modifiers, go to: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf	MYLOTARG for injection is a white to off-white lyophilized cake or powder supplied in a carton containing one 4.5-mg single-dose vial. Note: 1 unit of J9203 is 0.1 mg. 1 vial equals 45 units of J9203.
Diagnosis[4] **(ICD-10-CM)**	N/A	• C92.00 - Acute myeloblastic leukemia, not having achieved remission OR • C92.01 - Acute myeloblastic leukemia, in remission OR • C92.02 - Acute myeloblastic leukemia, in relapse	Include appropriate ICD-10-CM diagnosis code(s) for patient condition.
Administration[3,5] **(CPT Codes)**	Include appropriate revenue code for the cost center in which the service is performed.	• 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug AND • 96415 - Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)	Include appropriate ICD-10-PCS code(s) for product administration service. MYLOTARG is generally administered as a 2-hour IV infusion. Please refer to the full Prescribing Information for complete Dosage and Administration instructions.

Call Pfizer Oncology Together for billing and coding questions at 1-877-744-5675 or visit www.PfizerOncologyTogether.com

The information provided in this document is intended for informational purposes only, and is not a comprehensive description of potential coding requirements for MYLOTARG. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided in this section should not be considered a guarantee of coverage or reimbursement for MYLOTARG.

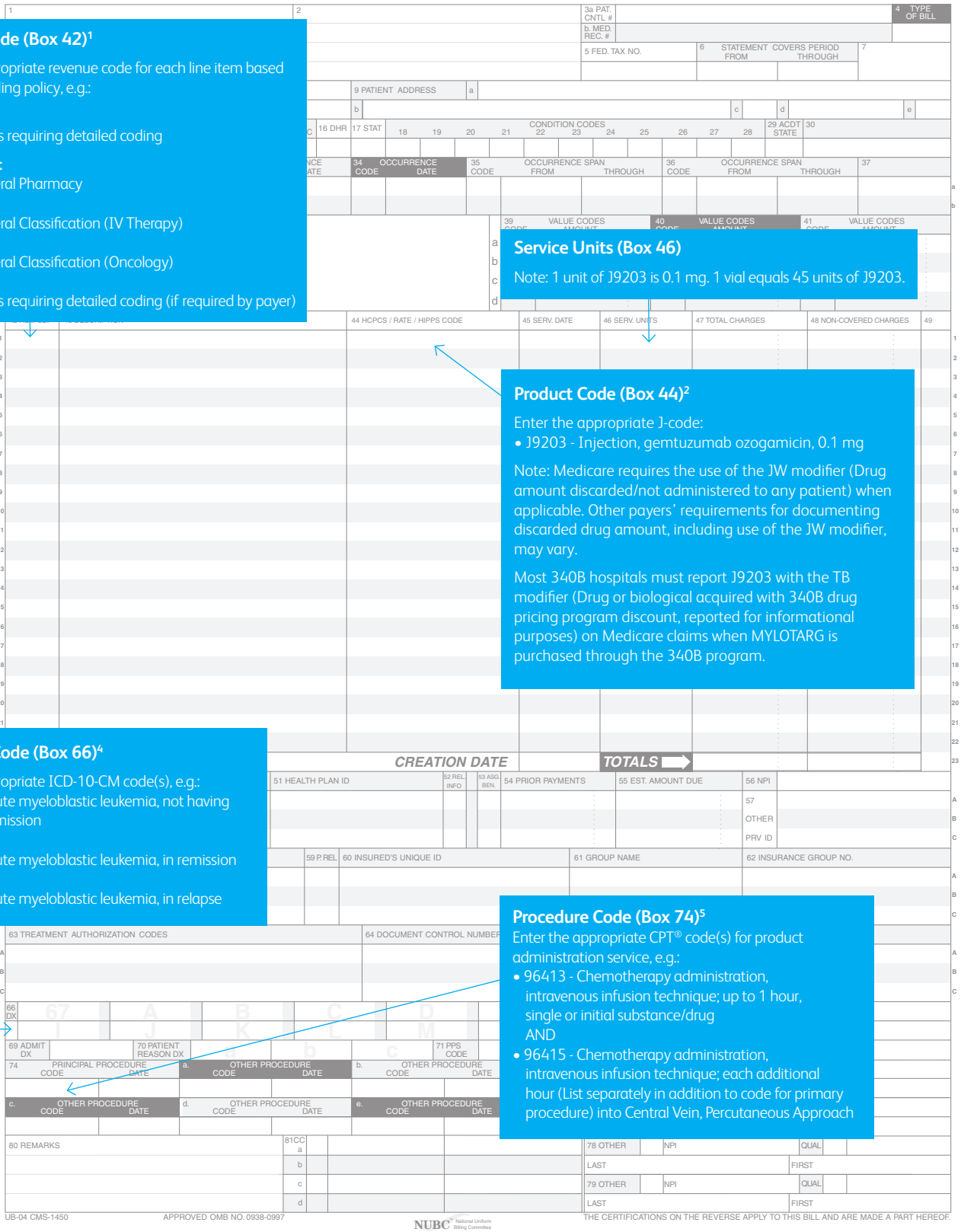
SELECTED SAFETY INFORMATION

WARNING: Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of MYLOTARG as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with MYLOTARG.

Please see Important Safety Information on page 3.
Please see full Prescribing Information, including BOXED WARNING, for MYLOTARG (gemtuzumab ozogamicin), available on MylotargHCP.com.

MYLOTARG™ gemtuzumab ozogamicin INJECTION FOR IV INFUSION 4.5 mg single-dose vial

UB-04/CMS-1450 FOR HOSPITAL OUTPATIENT[6]



Revenue Code (Box 42)[1]

Enter the appropriate revenue code for each line item based on hospital billing policy, e.g.:

Medicare:
- 0636 - Drugs requiring detailed coding

Other payers:
- 0250 - General Pharmacy
  OR
- 0260 - General Classification (IV Therapy)
  OR
- 0280 - General Classification (Oncology)
  OR
- 0636 - Drugs requiring detailed coding (if required by payer)

Service Units (Box 46)

Note: 1 unit of J9203 is 0.1 mg. 1 vial equals 45 units of J9203.

Product Code (Box 44)[2]

Enter the appropriate J-code:
- J9203 - Injection, gemtuzumab ozogamicin, 0.1 mg

Note: Medicare requires the use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers' requirements for documenting discarded drug amount, including use of the JW modifier, may vary.

Most 340B hospitals must report J9203 with the TB modifier (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) on Medicare claims when MYLOTARG is purchased through the 340B program.

Diagnosis Code (Box 66)[4]

Enter the appropriate ICD-10-CM code(s), e.g.:
- C92.00 - Acute myeloblastic leukemia, not having achieved remission
  OR
- C92.01 - Acute myeloblastic leukemia, in remission
  OR
- C92.02 - Acute myeloblastic leukemia, in relapse

Procedure Code (Box 74)[5]

Enter the appropriate CPT® code(s) for product administration service, e.g.:
- 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
  AND
- 96415 - Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) into Central Vein, Percutaneous Approach

CPT® is a registered trademark of the American Medical Association.

This sample form is intended as a reference for the coding and billing of MYLOTARG. This form is not intended to be directive and the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice patterns, and the services rendered.

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MYLOTARG™
gemtuzumab ozogamicin INJECTION FOR IV INFUSION
4.5 mg single-dose vial

INDICATIONS

MYLOTARG™ (gemtuzumab ozogamicin) is indicated for the treatment of newly diagnosed CD33-positive acute myeloid leukemia (AML) in adults, and relapsed or refractory CD33-positive AML in adults and pediatric patients 2 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of MYLOTARG as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with MYLOTARG.

Contraindications: Hypersensitivity to MYLOTARG or any of its components. Reactions have included anaphylaxis.

Hepatotoxicity, Including Veno-occlusive Liver Disease (VOD): Hepatotoxicity, including life-threatening and sometimes fatal hepatic VOD events, have been reported in patients receiving MYLOTARG as a single agent or as part of a combination chemotherapy regimen. Based on an analysis across trials, the risk of VOD was higher in adult patients who received higher doses of MYLOTARG as monotherapy, in patients with moderate or severe hepatic impairment prior to receiving MYLOTARG, in patients treated with MYLOTARG after HSCT, and in patients who underwent HSCT after treatment with MYLOTARG. Although no relationship was found between VOD and time of HSCT relative to higher MYLOTARG monotherapy doses, the ALFA-0701 study recommended an interval of 2 months between the last dose of MYLOTARG and HSCT. Assess ALT, AST, total bilirubin, and alkaline phosphatase prior to each dose of MYLOTARG. After treatment with MYLOTARG, monitor frequently for signs and symptoms of VOD; these may include elevations in ALT, AST, and total bilirubin, hepatomegaly, rapid weight gain, and ascites. Monitoring only total bilirubin may not identify all patients at risk of VOD. For patients who develop abnormal liver tests, more frequent monitoring of liver tests and clinical signs and symptoms of hepatotoxicity is recommended. For patients who proceed to HSCT, monitor liver tests frequently during the post-HSCT period, as appropriate. Manage signs or symptoms of hepatic toxicity by dose interruption or discontinuation of MYLOTARG. In patients who experience VOD, discontinue MYLOTARG and treat according to standard medical practice.

Infusion-Related Reactions (Including Anaphylaxis): Life-threatening or fatal infusion-related reactions can occur during or within 24 hours following infusion of MYLOTARG. Signs and symptoms of infusion-related reactions may include fever, chills, hypotension, tachycardia, hypoxia, and respiratory failure. Premedicate prior to MYLOTARG infusion. Monitor vital signs frequently during infusion. Interrupt infusion immediately for patients who develop evidence of infusion reaction, especially dyspnea, bronchospasm, or hypotension. Monitor patients during and for at least 1 hour after the end of the infusion or until signs and symptoms completely resolve. Discontinue use of MYLOTARG in patients who develop signs or symptoms of anaphylaxis, including severe respiratory symptoms or clinically significant hypotension.

Hemorrhage: MYLOTARG is myelosuppressive and can cause fatal or life-threatening hemorrhage due to prolonged thrombocytopenia. In ALFA-0701, (MYLOTARG in combination with chemotherapy), all grades and Grade 3-4 bleeding events were reported in 118/131 (90%) and 27/131 (21%) patients, respectively. Fatal bleeding events (including cerebral hematoma, intracranial hematoma, and subdural hematoma) occurred in 4/131 (3%) patients. The proportion of patients with persistent thrombocytopenia increased with progressive treatment phases and was higher in patients treated with MYLOTARG plus chemotherapy than with chemotherapy alone. Assess blood counts prior to each dose of MYLOTARG and monitor blood counts frequently after treatment with MYLOTARG until resolution of cytopenias. Monitor patients for signs and symptoms of bleeding during treatment with MYLOTARG. Manage severe bleeding, hemorrhage, or persistent thrombocytopenia using dose delay or permanent discontinuation of MYLOTARG, and provide supportive care per standard practice.

QT Interval Prolongation: QT interval prolongation has been observed in patients treated with other drugs containing calicheamicin. When administering MYLOTARG to patients who have a history of or predisposition for QTc prolongation, who are taking medicinal products that are known to prolong QT interval, and in patients with electrolyte disturbances, obtain electrocardiograms and electrolytes prior to the start of treatment and as needed during administration.

Adverse Cytogenetics: In a subgroup analysis in ALFA-0701, the addition of MYLOTARG to standard combination chemotherapy did not improve event-free survival in the subgroup of patients having adverse-risk cytogenetics. For patients being treated with MYLOTARG in combination with daunorubicin and cytarabine for newly diagnosed de novo AML, when cytogenetics testing results become available consider whether the potential benefit of continuing treatment with MYLOTARG outweighs the risks for the individual patient.

Embryo-Fetal Toxicity: MYLOTARG can cause embryo-fetal harm when administered to a pregnant woman. Advise patients of reproductive potential to use effective contraception during and for 3 and 6 months following treatment for males and females, respectively. Apprise pregnant women of the potential risk to the fetus. Advise women to contact their healthcare provider if they become pregnant or if pregnancy is suspected during treatment with MYLOTARG.

Adverse Reactions: All grade treatment-emergent adverse events (>15%) in patients exposed to MYLOTARG 3 mg/m^2 on Days 1, 4, and 7 as monotherapy included fever (79%), infection (42%), increased AST (40%), bleeding (23%), nausea and vomiting (21%), constipation (21%), mucositis (21%), headache (19%), increased ALT (16%), and rash (16%).

Please see full Prescribing Information, including BOXED WARNING, for MYLOTARG (gemtuzumab ozogamicin), available on MylotargHCP.com.

References: 1. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r167cp.pdf. CMS Manual System Pub 100-04/Transmittal 167. Published April 30, 2004. Accessed January 17, 2018. **2.** Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-Alpha-Numeric-HCPCS-File-.html Published January 2018. Accessed January 17, 2018. **3.** MYLOTARG Prescribing Information. New York, NY: Pfizer Inc. **4.** Centers for Medicare & Medicaid Services website. *ICD-10-CM Tabular List of Diseases and Injuries*. https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html. Accessed January 17, 2018. **5.** Hollmann PA, et al, eds. *Current Procedural Terminology*. 4th rev ed. Chicago, IL: American Medical Association; 2015. **6.** Centers for Medicare & Medicaid Services website. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r1104cp.pdf. CMS Manual System Pub 100-04/Transmittal 1104. Published November 3, 2006. Accessed January 17, 2018.

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