

**Billing Information for  
MOZOBIL<sup>®</sup> (plerixafor injection)**



This guide is intended solely for educational purposes and, specifically, to assist hospital and physician office billing staff with reimbursement issues. Any decision about whether and how to seek reimbursement should be made solely by the appropriate members of the billing staff in consultation with the physician and in light of the procedure performed on the patient, as well as the patient's diagnosis. Sanofi U.S. does not recommend or endorse the use of any particular procedure or diagnosis code(s). Please remember that reimbursement codes and billing requirements are subject to change.

The information provided in this guide is current as of July 18, 2013.



# Introduction and Product Overview

MOZOBIL® (plerixafor injection), a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

MOZOBIL is administered as a subcutaneous injection (under the skin) approximately 11 hours prior to each apheresis session (stem cell collection), up to a total of 4 days. As stated above, MOZOBIL is approved for use in combination with G-CSF. G-CSF is administered daily for 4 days prior to the first dose of MOZOBIL and on each morning prior to apheresis.

This billing guide is intended to provide up-to-date information about coding, reimbursement, and payment for MOZOBIL in 2012. 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 MOZOBIL in the hospital outpatient and physician office settings. In addition, the guide assists providers in documenting medical necessity and explains how providers can utilize MOZOBILDirect for reimbursement support.

It is important to note that this billing guide provides reimbursement information for MOZOBIL and the services directly related to its administration. It does not address coverage and payment for other services related to stem cell transplantation.

## **Important Safety Information for Mozobil (plerixafor injection)**

- Mozobil is contraindicated in patients with a history of hypersensitivity to Mozobil.
- Anaphylactic shock and serious hypersensitivity reactions, some of which have been life-threatening, have occurred in patients receiving Mozobil. Observe patients for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable. Only administer Mozobil when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*

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# MOZOBILDirect Reimbursement Assistance

Sanofi has a reimbursement support program to provide you with a 1-stop resource for all patient access and reimbursement needs. MOZOBILDirect is available weekdays (Monday - Friday) from 9:00 AM to 8:00 PM Eastern Time.

MOZOBILDirect can provide your office with assistance with the following complimentary services:

## **Insurance verification**

- to research coverage for MOZOBIL® (plerixafor injection)

## **Coding and billing assistance**

- to ensure accurate codes are used before claim submission

## **Claim/denial and appeal assistance**

- to research appeal strategies and provide supporting documentation for the appeals process

## **Prior authorization assistance**

- to research steps required to obtain authorization, if needed

## **Patient Assistance Program**

- to provide assistance to patients with no insurance coverage who meet program criteria

## **Resource connections**

- with permission, counselors will contact patients directly and work with both patients and providers to determine if there are alternative services available

## **Drug replacement**

### **MOZOBILDirect**

**1-877-4MOZOBIL (1-877-466-9624), option 3**

**<http://www.mozobildirect.com/>**

### **Hours of operation:**

**Monday through Friday**

**9:00 AM - 8:00 PM ET**

## **Indication**

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## **Important Safety Information for Mozobil (plerixafor injection)**

- Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia.
- Mozobil in conjunction with G-CSF increases circulating leukocytes and HSC populations. White blood cell counts should be monitored during treatment.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

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# MOZOBIL<sup>®</sup> (plerixafor injection) Coverage

Payers generally cover drug therapies and procedures deemed medically necessary to treat a patient's condition. Although coverage policies can vary by payer, most payers consider a drug to be medically necessary when used according to the indications on the product label approved by the U.S. Food and Drug Administration (FDA). Please see the accompanying MOZOBIL full Prescribing Information.

However, in some cases, payers may require additional information to cover a drug for a specific patient. In these instances, it may be helpful to provide a statement of medical necessity to explain why the drug is appropriate for the patient. Please see Appendix A for a sample Letter of Medical Necessity for MOZOBIL.

When determining if a product or service is covered, it is important to distinguish between coverage and payment. A service or product can be "bundled," meaning that it is covered but not paid for separately. A service or product that falls under an all-inclusive payment mechanism like a case rate is one example. Many payers apply case rates to reimburse for stem cell transplants and related services. While MOZOBIL is frequently eligible for separate payment, in some circumstances payers may bundle reimbursement for MOZOBIL in their transplant case rates.

## Medicare Part A and Part B

Medicare Part A typically applies when a drug is administered in an inpatient hospital setting. Medicare Part B typically applies when a drug is administered in a hospital outpatient\* or physician office setting. MOZOBIL is likely to be covered under Medicare Part A or Part B when it is used for an FDA-approved indication.

Medicare contractors determine coverage for most drugs, including MOZOBIL, at the local level. In some cases, a Medicare contractor may issue a local coverage determination (LCD)—a formal coverage policy that outlines the specific criteria under which patients qualify for coverage, as well as specific documentation or information that may be required for claim submission. However, even if a contractor does not have an LCD for MOZOBIL, the contractor should still cover MOZOBIL when used in accordance with the FDA-approved label.

Over the past several years, the Centers for Medicare & Medicaid Services (CMS) has engaged in "Medicare contractor reform," which has involved replacing the contractors that historically have processed Part A and Part B claims with new A/B Medicare Administrative Contractors (MACs). Traditionally, Part A claims have been processed by Part A fiscal intermediaries (FIs), while Part B claims have been processed separately by Part B carriers; however, the new A/B MACs process both Part A and Part B claims for a given region (although Part A and Part B coverage policies still may be separate). While many MAC contracts have been awarded, not all regions have completed their MAC transitions. It is important to know which Medicare contractor serves your geographic territory to identify the relevant transition dates (if applicable), and to become familiar with the contractor's coverage policies.

\*Although hospital outpatient services technically fall under Part B, they are treated as Part A for claims processing and coverage purposes. For example, a Part A coverage policy would apply to a drug that is administered in the hospital outpatient setting.

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## Medicare Part D

Historically, Medicare covered physician-administered drugs under Part A or Part B. Since 2006, many medications not covered under Part A or Part B are now covered under Part D, which is Medicare's prescription drug benefit. Medicare Part D is administered by commercial payers, which contract with Medicare to offer drug coverage through stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDPs).

MOZOBIL® (plerixafor injection) may be covered under Part D when obtained through retail, mail-order, specialty, or other pharmacy outlets. In order for MOZOBIL to be accessed through Part D, the drug would need to be covered by a patient's specific Part D plan. Many Part D plans include MOZOBIL on their formularies; however, individual coverage will vary by plan, and prior authorization may be required. In some cases, a drug may be covered on a case-by-case basis through a plan's "exception process," even if it is not listed on the plan's formulary.

The Medicare Part D benefit was not intended to replace the Part A or Part B benefit. Therefore, when injectable drugs like MOZOBIL are administered in settings that historically were associated with Medicare Part A or Part B (for example, the hospital outpatient department or physician office), Part A or Part B coverage will continue to apply in most cases.

While coverage for MOZOBIL may be available under Part D, the administration services associated with MOZOBIL are not covered under this benefit. However, if MOZOBIL is accessed under Part D through a pharmacy outlet but administered in a hospital outpatient or physician office setting, the administration services still may be covered under Medicare Part A or Part B, respectively.

## Private Payers

Most private payers cover FDA-approved drugs and biologicals when their use is 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 payers have medical criteria for coverage similar to those used by Medicare, while others develop their own policies. Furthermore, some private payers may apply utilization controls such as prior authorization before covering MOZOBIL, or may require that MOZOBIL be acquired through a specialty pharmacy. (See pp. 17-18 for additional information about specialty pharmacies.)

In some cases, MOZOBIL may be covered as part of a bundled payment for multiple healthcare services (such as a case rate payment) and would not be paid separately.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

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## Medicaid

Medicaid coverage policies are determined on a state-by-state basis. While some state Medicaid programs follow Medicare's guidelines for MOZOBIL, other programs may provide more limited benefits. Some state programs may also have prior authorization or specialty pharmacy requirements for MOZOBIL.

In some cases, MOZOBIL may be covered as part of a bundled payment for multiple healthcare services (such as a case rate, ambulatory payment group, or per-visit/per-diem payment) and may not be paid for separately outside of the bundled payment.

**NOTE:** To verify a specific payer's coverage policies for MOZOBIL, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

## Indication

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## Important Safety Information for Mozobil (plerixafor injection)

- Thrombocytopenia has been observed in patients receiving Mozobil. Platelet counts should be monitored in patients who receive Mozobil and then undergo apheresis.
- In patients treated with Mozobil in combination with G-CSF for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of potential reinfusion of tumor cells has not been well-studied.

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# MOZOBIL® (plerixafor injection) Coding

Coding systems provide a uniform language for describing medical, surgical, and diagnostic services; patient conditions; and certain drugs and supplies. Correct coding of all components of a service is necessary to obtain appropriate payment. Coding requirements will vary by payer and care setting. The relevant codes and coding systems for MOZOBIL are summarized in the table below, followed by a more detailed discussion on pp. 11-14.

Summary of MOZOBIL Coding		
Patient's Diagnosis*	ICD-9-CM: Multiple Myeloma	203.0X: Multiple myeloma
	ICD-9-CM: Non-Hodgkin's Lymphoma	200.0X: Reticulosarcoma
		200.1X: Lymphosarcoma
		200.2X: Burkitt's tumor or lymphoma
		200.3X: Marginal zone lymphoma
		200.4X: Mantle cell lymphoma
		200.5X: Primary central nervous system lymphoma
		200.6X: Anaplastic large cell lymphoma
		200.7X: Large cell lymphoma
		200.8X: Other named variants of lymphosarcoma and reticulosarcoma
		202.0X: Nodular lymphoma
		202.1X: Mycosis fungoides
		202.2X: Sézary's disease
		202.3X: Malignant histiocytosis
		202.4X: Leukemic reticuloendotheliosis
202.7X: Peripheral T-cell lymphoma		
202.8X: Other malignant lymphomas		
Drug	NDC	58468-0140-01: MOZOBIL (24-mg single-use vial)
	HCPCS	J2562: Injection, plerixafor, 1 mg
Professional Services	CPT**	96372: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
Hospital Services and Supplies	Revenue Codes	0250: General pharmacy
		0636: Drugs requiring detailed coding

*The codes in the table, as well as the coding information that follows, are provided solely for informational purposes and should not be construed as legal advice. The codes listed in this guide may not apply to all patients. This information is subject to change and interpretation, so it is important that you verify this information with your payer. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient, as well as the patient's actual diagnosis. You are ultimately responsible for the accuracy of the codes used to submit your claim.*

\*The fifth digit, X, identifies further specificity regarding disease location.

\*\*CPT codes, descriptions, and material only are copyright 2010 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein.

## Indication

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## Important Safety Information for Mozobil (plerixafor injection)

- Mozobil in conjunction with G-CSF increases circulating leukocytes and HSC populations. White blood cell counts should be monitored during treatment.

**Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>**

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## ICD-9-CM Diagnosis Codes

All hospital and physician office claim forms must include at least 1 International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code to describe the patient's condition. Some diagnosis codes that may apply to MOZOBIL patients treated for NHL or MM are included in the preceding table.

All ICD-9-CM diagnosis codes in this guide are provided only as examples of potentially relevant codes; providers should consult a current ICD-9-CM manual and always select the most appropriate diagnosis code(s) with the highest level of detail to describe a patient's actual condition. All diagnosis codes should be supported with adequate documentation in the patient's medical record.

## HCPCS Drug Code

MOZOBIL can be billed with a unique Healthcare Common Procedure Coding System (HCPCS) J-code, J2562 (Injection, plerixafor, 1 mg). For Medicare and many other payers, this code should be used to bill for MOZOBIL in the hospital outpatient and physician office settings. Providers should check with their private payers and state Medicaid program to verify appropriate coding for MOZOBIL.

HCPCS	Descriptor
J2562	Injection, plerixafor, 1 mg

When billing with HCPCS code J2562, providers must specify the total number of units administered to the patient on the claim form, in accordance with the code descriptor. Each single-use vial of MOZOBIL contains 24 mg; therefore, 24 units of J2562 must be billed to reflect a full single-use vial of MOZOBIL.

### MOZOBIL Billing Example:

24 mg (MOZOBIL single-use vial) x 1 billing unit per mg = 24 billing units of J2562

## Billing for Drug Wastage

Under Medicare's wastage policy, when a portion of a single-use vial must be discarded, providers may bill and receive payment for the amount of drug discarded as well as the dose administered, up to the total quantity of drug indicated on the vial or package label. (This policy does not apply to multiple-use vials.)

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Some local Medicare contractors may require the use of the modifier JW (drug amount discarded/not administered to any patient) to identify the quantity of drug from a single-use vial that is appropriately discarded. When the JW modifier is used, the drug is billed as 2 separate line items: one line item (without the JW modifier) would be used to report the quantity of drug administered, and the second line item (with the JW modifier) would be used to report the quantity of drug discarded.<sup>1</sup>

#### **EXAMPLE: Billing Medicare for MOZOBIL® (plerixafor injection) When JW Modifier Is Required**

**Reminder:** MOZOBIL is packaged in a 24-mg single-use vial and is billed per 1 mg using HCPCS code J2562.

**Scenario:** A provider administers 17 mg of MOZOBIL to a Medicare patient; the remaining 7 mg must be discarded.

**Line item 1:** 17 units of J2562 (no modifier) to report the quantity of drug administered

**Line item 2:** 7 units of J2562 with modifier JW to report the quantity of drug discarded

Many Medicare contractors do not require the JW modifier. When this modifier is not used, the drug is billed as a single line item with no modifier, and the number of units for the line item would represent the quantity of the drug administered plus the quantity of the drug discarded.

#### **EXAMPLE: Billing Medicare for MOZOBIL Without the JW Modifier**

**Reminder:** MOZOBIL is packaged in a 24-mg single-use vial and is billed per 1 mg using HCPCS code J2562.

**Scenario:** A provider administers 17 mg of MOZOBIL to a Medicare patient; the remaining 7 mg must be discarded.

**Line item 1:** 24 units of J2562 (no modifier) to report the quantity of drug administered plus the quantity of drug discarded

Regardless of whether the JW modifier is used, Medicare's payment policy is the same: when a portion of a single-use vial must be discarded, Medicare will pay for the quantity of drug administered plus the quantity discarded. Therefore, in both of the MOZOBIL examples described above, Medicare's payment to the provider would be based on 24 units of HCPCS code J2562.

It is important to note that the above examples are hypothetical scenarios. Providers always must determine the appropriate manner in which to address drug wastage in a specific situation. In addition, providers should appropriately document drug wastage in the patient's medical record. For example, one Medicare contractor requires that drug wastage "be documented in the patient's medical record with date, time, amount wasted, and reason for wastage."<sup>2</sup>

## **Indication**

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## **Important Safety Information for Mozobil (plerixafor injection)**

- The effect of Mozobil on spleen size was not specifically evaluated in clinical studies. Individuals receiving Mozobil in combination with G-CSF who report left upper abdominal pain and/or scapular or shoulder pain should be evaluated for splenic integrity.

**References:** 1. The Centers for Medicare and Medicaid Services. Change request 6711. *Discarded drugs and biologics updates*. April 30, 2010. <https://www.cms.gov/transmittals/downloads/R1962CP.pdf>. Accessed March 23, 2012. 2. Trailblazer Health Enterprises. Drug wastage. Published May 2010. <http://www.trailblazerhealth.com/Publications/Job%20Aid/Drug%20Wastage.pdf>. Accessed March 23, 2012.

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Although Medicare typically will reimburse for the discarded portion of a single-use vial, the policies of other payers may vary. Providers should check with their specific non-Medicare payers to determine their billing requirements regarding drug wastage, and should check with their local Medicare contractor to determine if the contractor requires the use of the JW modifier.

For assistance with determining payer- or contractor-specific billing requirements related to drug wastage, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

## CPT® Procedure Codes

Medicare and many other payers require that hospital outpatient and physician office claims contain appropriate Current Procedural Terminology (CPT)\* codes to identify procedures and services. Per 2011 CPT code guidelines, a single subcutaneous injection (nonchemotherapy) typically would be reported as 1 unit with the appropriate CPT code:

CPT	Descriptor
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

The appropriate CPT code for the administration of MOZOBIL will depend on the actual service performed. Providers should consult a current CPT manual and always select the code that accurately describes the administration service.

## Revenue Codes

All UB-04 hospital claim forms must include a revenue code for each line item. Revenue codes are 4-digit codes that allow hospitals to attribute supplies and services to specific cost centers within the facility. The following revenue codes are most relevant to MOZOBIL:

Revenue Code	Descriptor
0250	General pharmacy
0636	Drugs requiring detailed coding

Most HCPCS drug codes (including the J-code for MOZOBIL) must be reported with revenue code 0636 on Medicare hospital outpatient claims. Although some non-Medicare payers also accept revenue code 0636 in the hospital outpatient setting, others may require revenue code 0250. In addition, revenue code 0250 generally is used to report drugs in the hospital inpatient setting for Medicare and other payers. Each CPT procedure code also must be reported with a revenue code, which may vary depending on the type of procedure and the cost center in which the procedure is performed.

Revenue codes are not used on physician office claims.

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## NDCs

National drug codes (NDCs) typically are used to bill for drugs on pharmacy claims (for example, under Medicare Part D). Although NDCs are not used under Medicare Part A or Part B if a drug-specific HCPCS code is available (as is the case with MOZOBIL), some non-Medicare payers may require providers to report NDCs (sometimes in addition to HCPCS codes) on hospital outpatient or physician office claims; NDC-reporting requirements in these settings are especially common with state Medicaid programs.

The NDC for a 24-mg single-use vial of MOZOBIL is 58468-0140-01.

## Summary of Claim Submission Requirements

### Hospital Outpatient Setting

When MOZOBIL (plerixafor injection) is administered in the hospital outpatient setting, the hospital must submit a properly coded UB-04 claim form to obtain reimbursement for facility costs, including the drug and administration service(s). For Medicare and many other payers, the UB-04 claim must include codes for:

- The patient's diagnosis (ICD-9-CM code),
- The procedure(s) performed (CPT® code plus appropriate revenue code), and
- MOZOBIL (HCPCS code J2562 plus revenue code 0636 for Medicare claims)

### Physician Office Setting

When administering MOZOBIL in the physician's office, providers must submit a properly coded CMS-1500 claim form for the drug and associated service(s). Physician offices use many of the same coding systems as hospital outpatient departments—specifically, offices use HCPCS codes, CPT codes, and ICD-9-CM diagnosis codes, but not revenue codes. For Medicare and many other payers, the CMS-1500 claim must include codes for:

- The patient's diagnosis (ICD-9-CM code),
- The procedure(s) performed (CPT code), and
- MOZOBIL (HCPCS code J2562)

Accurate and specific coding is key to securing appropriate reimbursement. Billing codes that may be relevant to MOZOBIL are included above. In addition, sample claim forms are included in Appendix B (hospital outpatient) and Appendix C (physician office) of this guide.

**NOTE:** If you have questions about coding or would like assistance with determining payer-specific coding requirements for MOZOBIL, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

## Indication

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## Important Safety Information for Mozobil (plerixafor injection)

- Mozobil may cause fetal harm when administered to a pregnant woman. Plerixafor is teratogenic in animals. There are no adequate and well-controlled studies in pregnant women using Mozobil. Advise women of childbearing potential to avoid becoming pregnant while receiving treatment with Mozobil.
- The most common adverse reactions (≥10%) during HSC mobilization and apheresis were: diarrhea (37%), nausea (34%), fatigue (27%), injection site reactions (34%), headache (22%), arthralgia (13%), dizziness (11%), and vomiting (10%). The majority of these adverse reactions were Grade 1 or 2.

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# MOZOBIL<sup>®</sup> (plerixafor injection) Payment

Payment for MOZOBIL and associated services varies by payer and by setting. Most patients share in the cost of their medical care through deductibles, coinsurance, and/or copayments. The payment methodologies that may apply to MOZOBIL when administered in the hospital outpatient and physician office settings are described below.

## Hospital Outpatient Payment

### Medicare

Medicare pays for most hospital outpatient services using the hospital outpatient prospective payment system (OPPS). Under OPPS, separately payable items and services are assigned to ambulatory payment classification (APC) groups based on the CPT and HCPCS codes included on the UB-04 claim form. Each APC is associated with a fixed payment amount, which is intended to cover the facility's costs for services provided in the hospital outpatient setting.

In addition to Medicare's portion of the APC payment, hospitals also receive a set copayment from the patient (or the patient's secondary insurer). Physician services are reimbursed separately based on the Medicare physician fee schedule and are not included in APC payments to hospitals.

### Private Payers

Private payers use a variety of payment methodologies for drugs and biologicals in the hospital outpatient setting, including average wholesale price (AWP), average sales price (ASP), invoice, or percentage of charges. Private payer reimbursement mechanisms for drug administration services may include fee schedules, per-visit/per-diem rates, or percentage of charges. Additionally, some payers may reimburse for stem cell transplantation and related services based on a predetermined case rate, which may or may not include drug therapies such as MOZOBIL. The exact payment mechanism used by a specific payer usually depends on the hospital's contractual agreement with that payer.

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## Medicaid

Medicaid programs may pay for drugs and biologicals in the hospital outpatient setting based on AWP, ASP, ambulatory payment groups, state-specific fee schedules, preset per-diem/per-visit rates, or percentage of charges. Medicaid reimbursement mechanisms for administration services may include fee schedules, ambulatory payment groups, per-visit/per-diem rates, or percentage of charges. There is significant variation in Medicaid payment amounts among states; however, Medicaid programs typically pay less than other payers. As with private payers, some state Medicaid programs may use predetermined case rates to reimburse for stem cell transplantation and related services.

## Physician Office Payment

### Medicare

MOZOBIL® (plerixafor injection) is paid separately at ASP plus 4 percent when administered in the physician office setting. Under the ASP methodology, CMS calculates a payment amount for most drugs based on manufacturer-submitted sales data. Payment amounts under the ASP methodology are updated quarterly and may differ from one quarter to the next, based on the sales, discounts, and rebates that are reported to CMS.

Medicare reimburses for physician office services based on the resource-based relative value scale (RBRVS) physician fee schedule. This payment system also applies to physicians' professional services furnished in other care settings. Payment levels under the physician fee schedule are calculated separately for each covered CPT® code. RBRVS payment calculations take into account the average time, effort, practice expense, and malpractice cost associated with a procedure, as well as geographic cost differences. Most CPT codes relevant to the administration of MOZOBIL are eligible for separate RBRVS payments under the Medicare physician fee schedule.

For each separately payable drug or procedure in the physician office setting, Medicare pays 80 percent of the ASP or physician fee schedule amount, and the patient (or the patient's secondary payer) is responsible for the remaining 20 percent as coinsurance.

### Private Payers

Private payers use a variety of reimbursement methodologies for drugs and biologicals administered in the physician office setting, including AWP, ASP, invoice, or percentage of charges. Private payer reimbursement mechanisms for the administration procedure may be based on RBRVS or other fee schedules, or percentage of charges. Additionally, some payers may reimburse for stem cell transplantation and related services based on a predetermined case rate, which may or may not include drug therapies such as MOZOBIL.

### Medicaid

Medicaid programs may pay for MOZOBIL in the physician office setting based on AWP, ASP, state-specific fee schedules, or percentage of charges. Medicaid reimbursement mechanisms for the administration procedure may include RBRVS or other fee schedules, or percentage of charges. While Medicaid payment amounts vary significantly between states, Medicaid programs typically pay less than other payers. As with private payers, some state Medicaid programs may use predetermined case rates to reimburse for stem cell transplantation and related services.

**NOTE:** For assistance with determining the payment methodologies used by your specific payers, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*

## The Role of Specialty Pharmacies

In an effort to control costs and manage utilization, many payers have implemented specialty pharmacy requirements for injectable drugs such as MOZOBIL. Sometimes these requirements may apply even when drugs are administered in the hospital outpatient or physician office setting. Some payers require that providers obtain drugs like MOZOBIL through a specialty pharmacy, while others allow providers to choose between specialty pharmacy acquisition or the traditional “buy-and-bill” methodology (under which the provider purchases and stocks the drug, and then bills the payer for the drug). In some cases, injectable products are also available through mail order or traditional retail pharmacies, although this is less common than specialty pharmacy access.

When payers require that a drug like MOZOBIL be obtained through a specialty pharmacy, providers typically neither purchase nor bill for the product. Rather, the payer usually reimburses the specialty pharmacy directly. In this scenario, providers would bill only for the administration service(s) related to the drug.

### **Private Payers**

Private payers employ a variety of drug acquisition options for certain drugs, some of which can lower costs for the plan by allowing for volume discounts and other rebates. Common acquisition methods adopted by private payers include the following:

- The provider may be required to buy and bill for the product
- The provider may be required to obtain the product through a specialty pharmacy
- The provider may be allowed to choose between securing the product through a specialty pharmacy, or buying and billing for the product

### **Medicaid**

Some Medicaid programs contract with specialty pharmacies to manage and distribute physician-administered drugs such as MOZOBIL. Specialty pharmacy requirements and procedures vary from state to state. Like private payers, some Medicaid programs may require that a drug be obtained through a specialty pharmacy, or they may allow providers to choose between specialty pharmacy access or buying and billing.

### **Indication**

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM).

### **Important Safety Information for Mozobil (plerixafor injection)**

- Mozobil® is contraindicated in patients with a history of hypersensitivity to Mozobil.
- Anaphylactic shock and serious hypersensitivity reactions, some of which have been life-threatening, have occurred in patients receiving Mozobil. Observe patients for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable. Only administer Mozobil when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*



## Medicare Part D

As discussed earlier in this guide, the Medicare Part D benefit is administered by private payers, which offer drug coverage through stand-alone PDPs and MA-PDPs. When coverage for MOZOBIL (plerixafor injection) is available through Medicare Part D, PDPs, and MA-PDPs may require access through a specialty pharmacy. The provider or patient should contact the specific Part D plan to confirm the coverage status of MOZOBIL and determine acquisition options.

The Medicare Part D benefit was not intended to replace the Part A or Part B benefit. Therefore, when drugs such as MOZOBIL are administered in settings that were historically associated with Medicare Part A or Part B (the hospital outpatient department or physician office, for example), Part A or Part B coverage will continue to apply in most cases. Although specialty pharmacy access is not available under the traditional Part A or Part B benefit, these pharmacies sometimes may play a role in supplying hospital- or office-administered drugs for Medicare Advantage plans.

**NOTE:** Drug acquisition requirements and procedures will vary by payer, and also may vary by drug. For assistance with determining whether a specific payer has a specialty pharmacy requirement for MOZOBIL, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

## Indication

MOZOBIL® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

## Important Safety Information for Mozobil (plerixafor injection)

- Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia.
- Mozobil in conjunction with G-CSF increases circulating leukocytes and HSC populations. White blood cell counts should be monitored during treatment.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*

# Establishing Medical Necessity for MOZOBIL® (plerixafor injection)

Proper coding is crucial to obtaining appropriate reimbursement for MOZOBIL and its administration. Coverage is likely when MOZOBIL is used for an FDA-approved indication.

However, some payers may require additional information or documentation to determine whether they will cover a claim for MOZOBIL. If this is the case, you may wish to include the following items with your claim (or provide the items to the payer upon request):

- Letter of medical necessity from the attending physician to the payer
- MOZOBIL package insert
- Documentation of the drug's FDA approval
- Documentation of clinical evidence supporting the product's safety and efficacy
- Specific details of the patient's case history and clinical course

**NOTE:** A sample letter of medical necessity specific to MOZOBIL is available in Appendix A of this guide. For assistance in verifying a specific payer's documentation requirements for MOZOBIL, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*

# Instructions for Appealing Denied Claims for MOZOBIL® (plerixafor injection)

Some of the most common reasons for claim denial or underpayment include:

- Specific details of the patient's case history and clinical course
- Use of incorrect billing codes or failure to comply with special coding requirements
- Lack of documentation supporting choice of codes and/or medical necessity of services
- Omission of an accurate description of services

Payers deny coverage and claims for a variety of reasons, including variations in policies; confusion or lack of knowledge about the services provided; or technical billing errors, such as code omissions, misspellings, or transposed numbers. Therefore, it is important to include appropriate supporting information or documentation when requesting coverage for a patient, and to carefully review claims that have been denied to identify technical errors. When coverage or claims are denied, physicians, pharmacists, patients, and patients' families often can appeal successfully if the treatment is medically necessary and given for an appropriate indication. If a patient is denied coverage for MOZOBIL, you should consider the rights of the patient and family throughout the appeals process. For example, patients insured through an employer can begin the appeal in their personnel office. Patients insured by Medicare can contact their local Medicare contractor, Part D plan, or Medicare Advantage plan to inquire about their appeal rights. Patients insured by Medicaid can contact their state Medicaid program office or Medicaid managed care plan to obtain information on appeals.

The following steps may serve as a guide for appealing coverage or claim denials:

**Step 1.** Review the payer's rationale for the denial. Discuss the reason for denial with the payer. Claims are often denied because the payer is not familiar with the product or procedure or because the claim is missing identification numbers, patient names, or signatures. Review the claim for submission errors.

**Step 2.** If claim submission errors have been ruled out, and/or if the payer denied coverage because medical necessity was not sufficiently supported, you will need to submit documentation to justify the medical necessity of the drug. Your appeal must be submitted within the time limits specified by the payer. Submit a letter of medical necessity with the appeal. Make sure the letter highlights the following information:

- The patient's medical history
- Other therapies that have been tried without success
- Reasons the drug was recommended for this particular patient
- Risks of forgoing therapy with the recommended drug

In addition, include the following information with the resubmitted claim:

- The drug package insert
- Any relevant peer-reviewed clinical articles
- The FDA drug approval letter

**Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>**

**For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.**

**Step 3.** If you receive a second denial, please advise the patient to call the payer’s medical director or claims manager to request another review or a hearing. You may be asked for a copy of all the paperwork, so be prepared to resubmit the materials. Note that this step is not applicable under Medicare; rather, the individual will need to appeal to the next appropriate level.

**Step 4.** Encourage patients to contact their benefits office when coverage is denied and talk to the benefits manager if necessary. Although the appeal process may be lengthy, remember that many efforts to pursue coverage and payment are successful. Efforts for one patient may ensure that the next patient will not experience similar problems with the payer.

**NOTE:** A sample letter of appeal for denied claims, specific to MOZOBIL, is available in Appendix D of this guide. For assistance in appealing a denied claim for a specific payer, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*



## *Appendices*

## Appendix A: Sample Letter of Medical Necessity

This sample letter is intended as a general guide for submitting information to payers to substantiate medical necessity. For additional assistance in medical necessity documentation, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3. It is solely your responsibility to ensure the accuracy and completeness of the letter as it pertains to your specific patients.

[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 MOZOBIL® (plerixafor injection) therapy as a result of [insert medical diagnosis]. MOZOBIL (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). MOZOBIL was approved by the U.S. Food and Drug Administration (FDA) on December 15, 2008.

This letter provides information on the patient's medical history and treatment, the MOZOBIL 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 MOZOBIL and the treatment rationale (ie, why this product and procedure were chosen for this particular patient)].

I hope that this letter has been helpful in explaining the advantages and clinical benefits of MOZOBIL therapy and its value for this patient. The MOZOBIL 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.

Please see accompanying full Prescribing Information.

Sincerely,  
[Physician's name]

### Important Safety Information for Mozobil (plerixafor injection)

- Mozobil is contraindicated in patients with a history of hypersensitivity to Mozobil.
- Anaphylactic shock and serious hypersensitivity reactions, some of which have been life-threatening, have occurred in patients receiving Mozobil. Observe patients for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable. Only administer Mozobil when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*



# Appendix C:

## Sample Physician Office Claim Form CMS-1500 (08-05)

This document is provided for your guidance only. This form may change over time, so you will need to check with your payer to make sure you are using the most current form. Please call MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624) and select option 3 for assistance in verifying coding and claim information for specific payers. The information provided in these forms and provided over the phone should you call the listed number does not constitute legal advice and it is incumbent upon you to independently verify the coding/claim information with your payer. Please remember it is your sole obligation to accurately reflect the services and products furnished to the patient, the patient's actual diagnosis, and the coding and claim information submitted to the payer.

**1500**  
**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

**Physician Office**  
**Sample CMS-1500 (08-05)**  
**Mozobil® (plerixafor injection)**

1. MEDICARE (Medicare #) <input type="checkbox"/> MEDICAID (Medicaid #) <input type="checkbox"/> TRICARE (Sponsor's SSN) <input type="checkbox"/> CHAMPVA (Member ID#) <input type="checkbox"/> GROUP HEALTH PLAN (SSN or ID) <input type="checkbox"/> FECA (SSN) <input type="checkbox"/> OTHER (ID) <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE (MM   DD   YY) SEX (M   F)	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED (Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
CITY		7. INSURED'S ADDRESS (No., Street)	
STATE		8. PATIENT STATUS (Single <input type="checkbox"/> Married <input type="checkbox"/> Other <input type="checkbox"/>	
ZIP CODE		CITY	
TELEPHONE (Include Area Code)		STATE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) (YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. OTHER INSURED'S DATE OF BIRTH (MM   DD   YY) SEX (M   F)		b. AUTO ACCIDENT? (YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____	
c. EMPLOYER'S NAME OR SCHOOL NAME		c. OTHER ACCIDENT? (YES <input type="checkbox"/> NO <input type="checkbox"/>	
11. INSURED'S POLICY GROUP OR FECA NUMBER		a. INSURED'S DATE OF BIRTH (MM   DD   YY) SEX (M   F)	
11. INSURED'S POLICY GROUP OR FECA NUMBER		b. EMPLOYER'S NAME OR SCHOOL NAME	
11. INSURED'S POLICY GROUP OR FECA NUMBER		c. INSURANCE PLAN NAME OR PROGRAM NAME	

**Box 21: Diagnosis Code**  
Enter the appropriate ICD-9-CM diagnosis code.

**Note:** Enter the appropriate diagnosis as reflected in the patient's medical record.

**Box 24G: Days or Units**  
Enter the appropriate number of units.

**Example:** Each single use vial of MOZOBIL contains 24 mg or 24 units of J2562. 24 units of MOZOBIL must be billed to reflect a full single dose vial.

**Note:** 24 mg product X 1 billing unit per mg = 24 billing units.

14. DATE OF CURRENT ILLNESS (First 5/09/2009) OR INJURY (Accident) OR PREGNANCY(LMP)		15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE (MM   DD   YY)	
17a. NAME OF REFERRING PROVIDER OR OTHER SOURCE		17b. NPI	
19. RESERVED FOR LOCAL USE			
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)		20. OUTSIDE LAB? (YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____)	
1. J203.01		22. MEDICAID RESUBMISSION ORIGINAL REF. NO. _____	
2. _____		23. PRIOR AUTHORIZATION NUMBER _____	
24. A. DATE(S) OF SERVICE (From To) B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. REFILL I. QUAL. J. RENDERING PROVIDER ID. #			
1. MM   DD   YY   MM   DD   YY   11   J2562   1   XX   XX   24   NPI			
2. MM   DD   YY   MM   DD   YY   11   96372   1   XX   XX   1   NPI			
3. _____			
4. _____			
5. _____			
6. _____			

**Box 24D: Procedures, Services, or Supplies**  
Enter appropriate HCPCS code.  
Enter appropriate CPT codes for drug administration services.

25. FEDERAL TAX I.D. NUMBER		26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE		29. AMOUNT PAID		30. BALANCE DUE	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER (Including Degrees or Credentials)		32. SERVICE FACILITY LOCATION INFORMATION		33. BILLING PROVIDER INFO & PH #							
SIGNED _____ DATE _____		a. _____ b. _____		a. _____ b. _____							

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org) APPROVED OMB-0938-0999 FORM CMS-1500 (08/05)

Please see accompanying full Prescribing Information.

Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>

For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.

## Appendix D: Sample Letter of Appeal for Denied Claims

This sample letter is intended as a general guide for requesting reconsideration for denied claims. For additional assistance concerning the appeals process, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.

[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 formally appeal 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, MOZOBIL® (plerixafor injection) therapy was medically necessary. This letter provides my clinical rationale for MOZOBIL therapy. It presents information about this patient's medical condition, discusses MOZOBIL indications and the administration procedure, and explains why it was medically necessary and appropriate for this patient.

MOZOBIL (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). MOZOBIL was approved by the U.S. Food and Drug Administration (FDA) on December 15, 2008.

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

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

I hope that this letter has been helpful in explaining the medical necessity of MOZOBIL 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 MOZOBIL therapy and its clinical benefits, and
- [Any additional relevant information to support the appeal, such as medical notes or payer policy]

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

Please see accompanying full Prescribing Information.

Sincerely,  
[Physician's name]

### Important Safety Information for Mozobil (plerixafor injection)

- Mozobil is contraindicated in patients with a history of hypersensitivity to Mozobil.
- Anaphylactic shock and serious hypersensitivity reactions, some of which have been life-threatening, have occurred in patients receiving Mozobil. Observe patients for signs and symptoms of hypersensitivity during and after Mozobil administration for at least 30 minutes and until clinically stable. Only administer Mozobil when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

*Please see additional Important Safety Information on last page and Full Prescribing Information at <http://products.sanofi.us/Mozobil/mozobil.html>*

*For additional questions, please contact MOZOBILDirect at 1-877-4MOZOBIL (1-877-466-9624), option 3.*



## Indication

Mozobil® (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

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- Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia.
- Mozobil in conjunction with G-CSF increases circulating leukocytes and HSC populations. White blood cell counts should be monitored during treatment.
- Thrombocytopenia has been observed in patients receiving Mozobil. Platelet counts should be monitored in patients who receive Mozobil and then undergo apheresis.
- In patients treated with Mozobil in combination with G-CSF for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of potential reinfusion of tumor cells has not been well-studied.
- The effect of Mozobil on spleen size was not specifically evaluated in clinical studies. Individuals receiving Mozobil in combination with G-CSF who report left upper abdominal pain and/or scapular or shoulder pain should be evaluated for splenic integrity.
- Mozobil may cause fetal harm when administered to a pregnant woman. Plerixafor is teratogenic in animals. There are no adequate and well-controlled studies in pregnant women using Mozobil. Advise women of childbearing potential to avoid becoming pregnant while receiving treatment with Mozobil.
- The most common adverse reactions ( $\geq 10\%$ ) during HSC mobilization and apheresis were: diarrhea (37%), nausea (34%), fatigue (27%), injection site reactions (34%), headache (22%), arthralgia (13%), dizziness (11%), and vomiting (10%). The majority of these adverse reactions were Grade 1 or 2.

*Please see Full Prescribing Information at [www.mozobil.com](http://www.mozobil.com)*