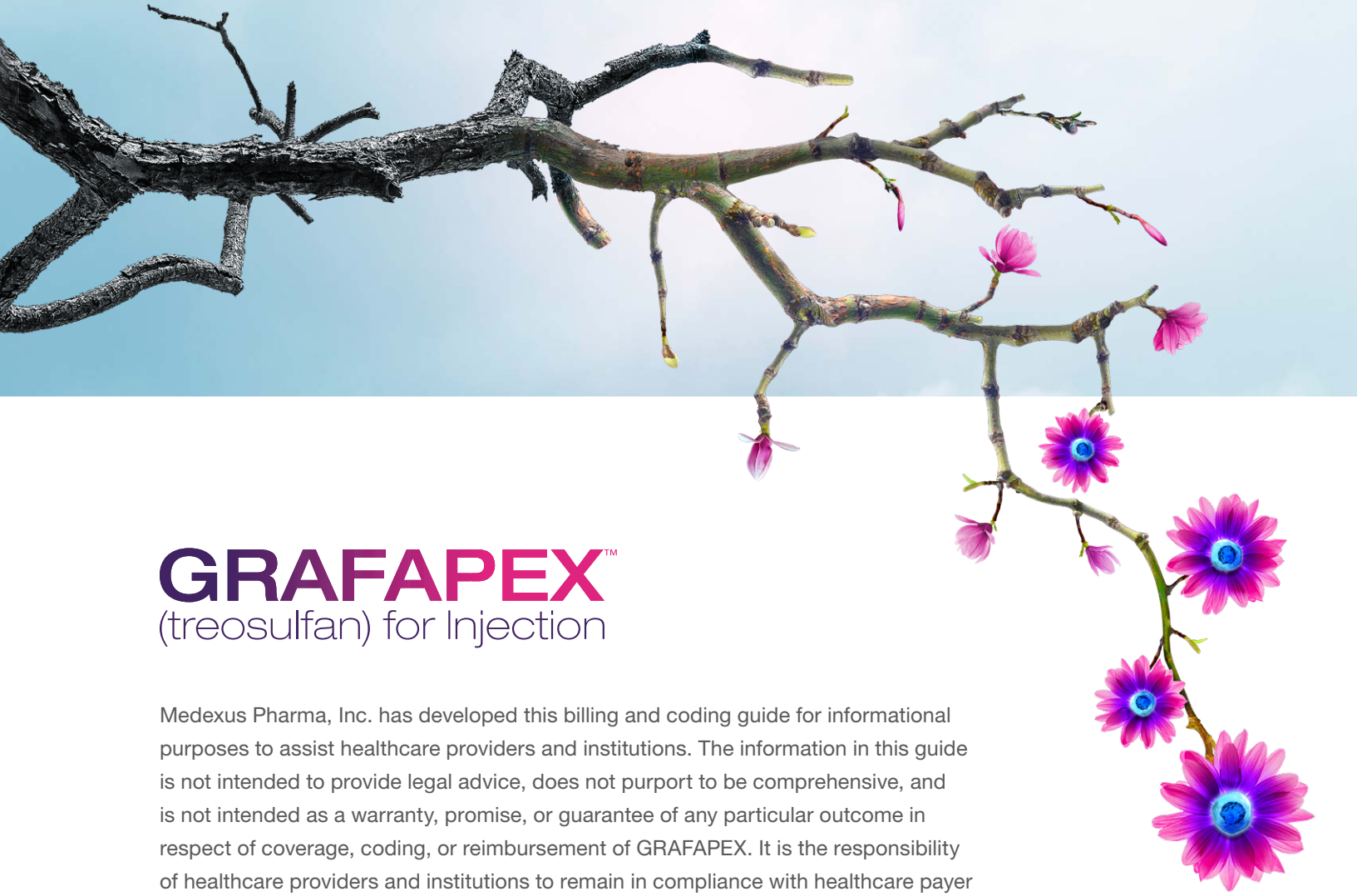
Billing & Coding Guide

for GRAFAPEX™ (treosulfan) for Injection



GRAFAPEX™
(treosulfan) for Injection

Medexus Pharma, Inc. has developed this billing and coding guide for informational purposes to assist healthcare providers and institutions. The information in this guide is not intended to provide legal advice, does not purport to be comprehensive, and is not intended as a warranty, promise, or guarantee of any particular outcome in respect of coverage, coding, or reimbursement of GRAFAPEX. It is the responsibility of healthcare providers and institutions to remain in compliance with healthcare payer guidelines, requirements, and policies relevant to coverage, coding, and reimbursement of GRAFAPEX. For clarity, the information in this guide is not intended to increase or maximize reimbursement by any payer.

For more information, including ordering details and Full Prescribing Information, including boxed warning, please visit: https://www.GRAFAPEX.com.

Indications and Usage

Acute Myeloid Leukemia: GRAFAPEX is an alkylating drug indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients > 1 year old with acute myeloid leukemia.

Myelodysplastic Syndrome: GRAFAPEX is an alkylating drug indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients > 1 year old with myelodysplastic syndrome.

This product includes the following Boxed Warning:

WARNING: MYELOSUPPRESSION

- **GRAFAPEX causes severe and prolonged myelosuppression at the recommended dosage.**
- **Hematopoietic stem cell transplantation is required to prevent potentially fatal complications of the prolonged myelosuppression. Monitor hematologic laboratory parameters.**

Warnings and Precautions

Myelosuppression: Profound myelosuppression with pancytopenia is the desired therapeutic effect of a GRAFAPEX-based preparative regimen, occurring in all patients. Do not begin the preparative regimen if the stem cell donor is not available. Monitor blood cell counts at least daily until hematopoietic recovery. Provide standard supportive care for infections, anemia, and thrombocytopenia until there is adequate hematopoietic recovery.

Seizures: Monitor patients for signs of neurological adverse reactions, including seizures. Clonazepam prophylaxis may be considered for patients at higher risk for seizures, including infants.

Skin Disorders: An increase in skin disorders (eg, rash, dermatitis) was observed when patients received sodium bicarbonate-containing hydration in the course of treosulfan infusion. Keep skin clean and dry on days of GRAFAPEX infusion. Diaper dermatitis may occur because of excretion of treosulfan in the urine. Change diapers frequently during the 12 hours after each infusion of GRAFAPEX. Dermatitis may occur under occlusive dressings; change occlusive dressings after each infusion of GRAFAPEX.

Injection Site Reactions and Tissue Necrosis: Treosulfan may cause local tissue necrosis and injection site reactions, including erythema, pain, and swelling, in cases of extravasation. Assure venous access patency prior to starting GRAFAPEX infusion, and monitor the intravenous infusion site for redness, swelling, pain, infection, and necrosis during and after administration of GRAFAPEX. If extravasation occurs, stop the infusion immediately and manage medically as required. Do not administer by intramuscular or subcutaneous routes.

Secondary Malignancies: There is an increased risk of a secondary malignancy with the use of GRAFAPEX. Treosulfan is carcinogenic and genotoxic.

The risk of secondary malignancy is increased in patients with Fanconi anemia and other DNA breakage disorders. The safety of GRAFAPEX has not been established for patients with these disorders.

Increased Early Morbidity and Mortality at Dosages Higher Than Recommended: A higher incidence of early fatal and/or serious adverse reactions has been observed in patients receiving treosulfan at dosages of 14 g/m^2 (1.4 times the recommended dose). Avoid exceeding the recommended GRAFAPEX dosage of 10 g/m^2 daily for three consecutive days.

Embryo-Fetal Toxicity: GRAFAPEX can cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception.

Adverse Reactions

The most common adverse reactions (≥ 20%) in patients treated with GRAFAPEX were musculoskeletal pain, stomatitis, pyrexia, nausea, edema, infection, and vomiting. Select Grade 3 or 4 nonhematological laboratory abnormalities were increased GGT, increased bilirubin, increased ALT, increased AST, and increased creatinine.

Drug Interactions

Effect of GRAFAPEX on Other Drugs (Certain CYP2C19 and CYP3A Substrates): Concomitant use of GRAFAPEX is predicted to increase the exposure of CYP2C19 and CYP3A4 substrates based on a mechanistic understanding of treosulfan metabolism, which may increase the risk of adverse reactions.

Use in Specific Populations

Pregnancy: GRAFAPEX can cause fetal harm. There are no available human clinical data on the use of treosulfan in pregnant women to support an estimation of a drug-associated risk. Specific embryo-fetal developmental toxicity studies with treosulfan in animals were not conducted.

Lactation: There is no data on the presence of treosulfan or its metabolites in human milk, its effects on milk production, or the effects of treosulfan on the breastfed child. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with GRAFAPEX and for at least 1 week after the last dose.

Patients With Renal Impairment: No dosage adjustment is recommended for patients with mild renal impairment (creatinine clearance [CLcr] 60-89 mL/min). The effect of moderate or severe renal impairment and age > 65 years on GRAFAPEX pharmacokinetics is unknown.

Pediatric Use: The safety profile in children 1 year of age and older is comparable to that seen in adult patients, except that the incidence of hepatic and gastrointestinal toxicities was higher in pediatric patients than in adults.

Geriatric Use: No significant differences in safety or effectiveness were observed between elderly subjects and younger subjects.

Hepatic Impairment: No dosage adjustment is recommended for patients with mild hepatic impairment (total bilirubin less than or equal to upper limit of normal [ULN] with aspartate aminotransferase [AST] greater than ULN or total bilirubin greater than 1 to 1.5 times ULN with any AST). The effect of moderate or severe hepatic impairment and age > 65 years on GRAFAPEX pharmacokinetics is unknown.

For adverse events, medical inquiries, and GRAFAPEX product-related concerns, please call 1-855-336-3322.

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GRAFAPEX™ (treosulfan) for Injection

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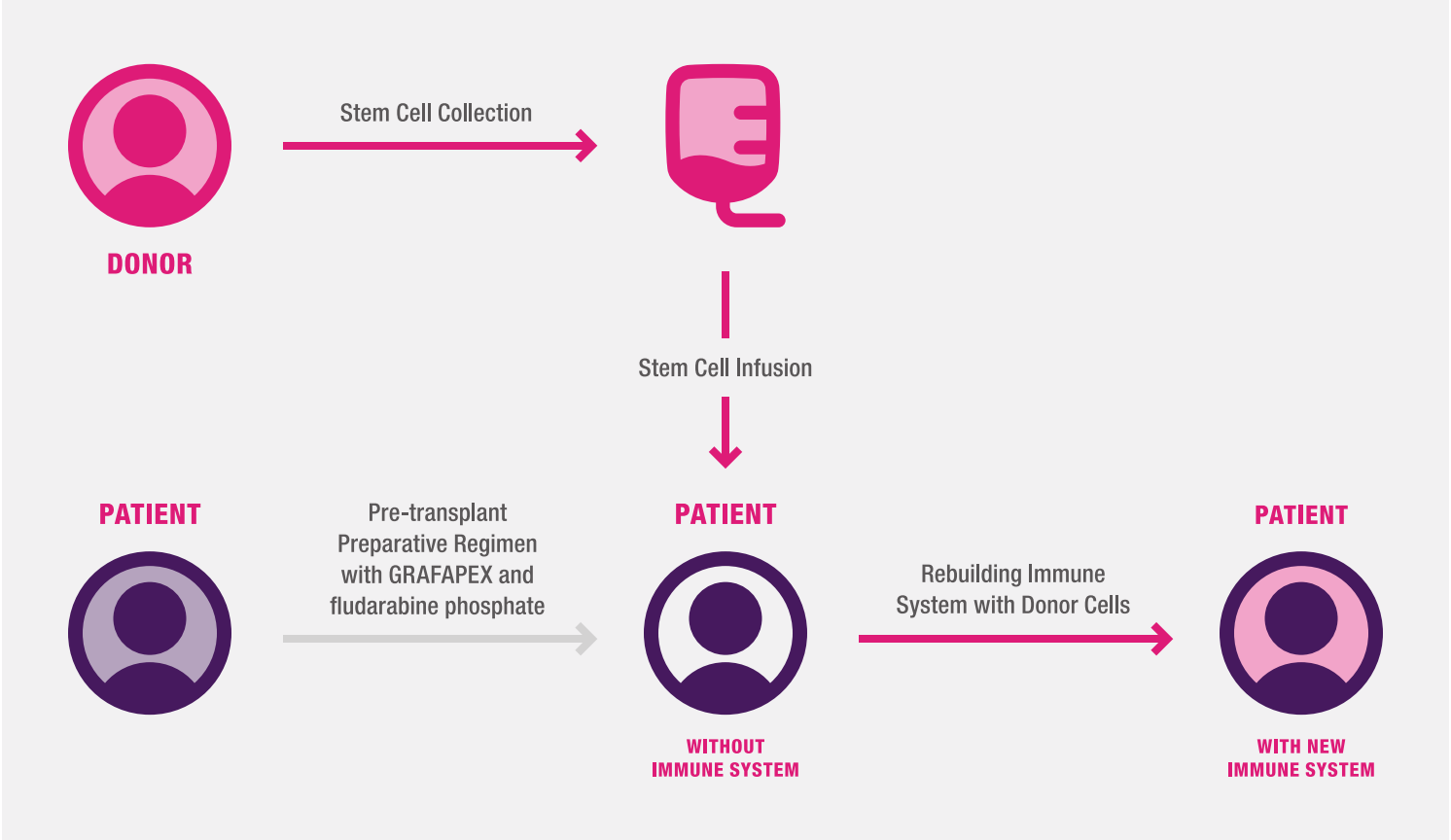
PATIENT CARE PROCESS[1]

GRAFAPEX™ (treosulfan) for Injection is indicated in combination with fludarabine phosphate as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).[1]



The recommended dosage of GRAFAPEX is 10 g/m^2 by intravenous infusion given daily for three days, beginning on Day -4 prior to transplantation in combination with fludarabine phosphate. Premedicate patients with antiemetics prior to the first dose of GRAFAPEX and continue antiemetics on a fixed schedule through completion of GRAFAPEX administration.[1]

Treatment[1]	Day -6	Day -5	Day -4	Day -3	Day -2	Day -1	Day 0
GRAFAPEX 10 g/m^2/day intravenously			**X**	**X**	**X**		
Fludarabine 30 mg/m^2/day intravenously	X	X	X	X	X		
Allogeneic hematopoietic stem cell infusion							X

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Allogeneic Hematopoietic Stem Cell Transplant Reimbursement

Allogeneic transplants are reimbursed under three primary methodologies: Medicare Severity Diagnosis Related Group (MS-DRG), All Patient Refined Diagnosis Related Group (APR-DRG) or transplant case rate. A payer's approval for an allogeneic transplant is based on the patient's clinical diagnosis and whether that is considered a covered indication for transplant by a payer. Generally, GRAFAPEX™ (treosulfan) for Injection will be bundled into the hospital payment rather than paid separately.[2] Examples of allogeneic transplant DRGs are listed below. A DRG payment covers the transplant procedure and related costs, including donor search and evaluation, and cell acquisition.[3] Only one payment methodology will be used and, if DRG-based, only one DRG payment will apply for a given inpatient admission.[2]

DRG Type	DRG	DRG Description
APR-DRG	007	Allogeneic Bone Marrow Transplant (with 4 levels of severity adjustment)[4]
MS-DRG	014	Allogeneic Bone Marrow Transplant[5]

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes

Hospitals use current ICD-10-CM codes to report a patient's diagnosis on claim forms.[6] Below is a range of potential ICD-10-CM diagnosis codes that may be related to a diagnosis within GRAFAPEX's approved label.[7,8] Included in the table are three Z-codes listed in the NCCN Drugs & Biologics Compendium (NCCN Compendium®) listing for (treosulfan) GRAFAPEX.[8] ICD-10-CM Z-codes (other reasons for healthcare encounters) may be assigned to further explain the reasons for presenting for healthcare services or to provide additional information relevant to a patient encounter.[6] Correct coding is the responsibility of the hospital submitting a claim for the item or service. Always check payer guidelines to verify diagnosis coding requirements as individual payer rules may vary and must be followed.

ICD-10-CM Code[7,8]	Diagnosis Code Description
C92.00	Acute myeloblastic leukemia, not having achieved remission
D46.9	Myelodysplastic syndrome, unspecified
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status
Z94.9	Transplanted organ and tissue status, unspecified

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International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS)[9]

Effective 10/01/2022, the Centers for Medicare & Medicaid Services (CMS) created ICD-10-PCS codes that identify the administration of GRAFAPEX during an inpatient admission. For additional information, please consult current ICD-10-PCS guidance. Always confirm adherence to specific payer rules and guidelines. GRAFAPEX, in combination with fludarabine phosphate, is being considered for New Technology Add-on Payment (NTAP) for FY 2026 which begins on 10/01/2025.[10] The purpose of the NTAP program is to incentivize the adoption of new technologies that have demonstrated significant clinical improvements.[2]

ICD-10 PCS Code	Inpatient Procedure Code Description
XW04388	Introduction of treosulfan into central vein, percutaneous approach, new technology group 8
XW03388	Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8

Revenue Codes[11,12]

Revenue codes are provided on both inpatient and outpatient claims for informational purposes only and may vary by hospital. Hospital Outpatient Prospective Payment System (OPPS) claims for drugs and biologicals should be billed with the appropriate HCPCS codes under revenue code 0636 (if they are considered separately payable or packaged).

Revenue Code	Revenue Code Description
0250	General pharmacy
0251	General pharmacy
0260	General IV therapy
0636	Drugs requiring detailed coding (hospital outpatient only)

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Level I CPT® (Current Procedural Terminology) and Level II Healthcare Common Procedure Coding System (HCPCS) Codes[12,13,14]

If GRAFAPEX is administered in the hospital outpatient setting, there may be separate reimbursement. Two HCPCS codes are primarily used. Level I CPT codes[12] describe the administration of GRAFAPEX.

CPT Code	CPT Code Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour

Level II HCPCS codes[13] describe the drugs themselves. Effective 07/01/2025 GRAFAPEX has been granted pass-through status, and a temporary C-Code (also known as a pass-through code) has been assigned for use in the Hospital Outpatient setting of care. An application for a permanent HCPCS code for GRAFAPEX has been submitted. Until assignment of a permanent HCPCS code, GRAFAPEX, when administered in a setting of care other than Hospital Outpatient, may be reported by using the Not Otherwise Classified (NOC) HCPCS code listed below.

HCPCS Code	HCPCS Code Description
J9999	Not otherwise classified, antineoplastic drugs
C9175	Injection, treosulfan, 50 mg (hospital outpatient only[14])
J9185	Injection, fludarabine phosphate, 50 mg

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National Drug Codes (NDCs)

Payers will likely require the NDC to be included on any insurance claim, whether for inpatient or outpatient administration. NDCs are universal product identifiers assigned to drugs upon FDA approval.[15] Drugs and biologics such as GRAFAPEX are assigned unique, 3-segment NDC numbers.[1] On drug packaging, NDC numbers are often displayed in a 10-digit format; however, claim filing requires an 11-digit NDC in a 5-4-2 format.[16] In the table below, the NDC code for GRAFAPEX has been "zero-filled" to ensure the creation of an 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards. The zero-fill location is indicated in bold, red font.

11-digit NDC	NDC Description
59137-**0**365-01	GRAFAPEX (treosulfan) for Injection – 5 gram
59137-**0**335-01	GRAFAPEX (treosulfan) for Injection – 1 gram
XXXXX-XXXX-XX*	fludarabine phosphate

**Fludarabine phosphate NDC and appropriate zero-fill location will vary by product manufacturer*

For more information, including ordering details and Full Prescribing Information, including boxed warning, please visit: https://www.GRAFAPEX.com.

Sample Hospital Inpatient Claim Form: CMS-1450/UB-04[17,18]

Field Locator (FL) 42
Input appropriate revenue code such as 0250 – general pharmacy

FL 43
Input procedure description such as treosulfan and fludarabine phosphate

FL 44
Input HCPCS code such as J9999 (not otherwise classified, antineoplastic) and J9185

FL 45
Input date of service (MMDDYYYY)

FL 46
Input service units (most payers require 1 unit when using a Not Otherwise Classified [NOC] code)

FL 47
Input total charges

FL 69-70
Input admitting diagnosis code(s) (DX) for a diagnosis covered for allogeneic HSCT

FL 74 & 74a
Input the ICD-10-PCS code for the relevant procedures, including, for example, XW03388 - Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8

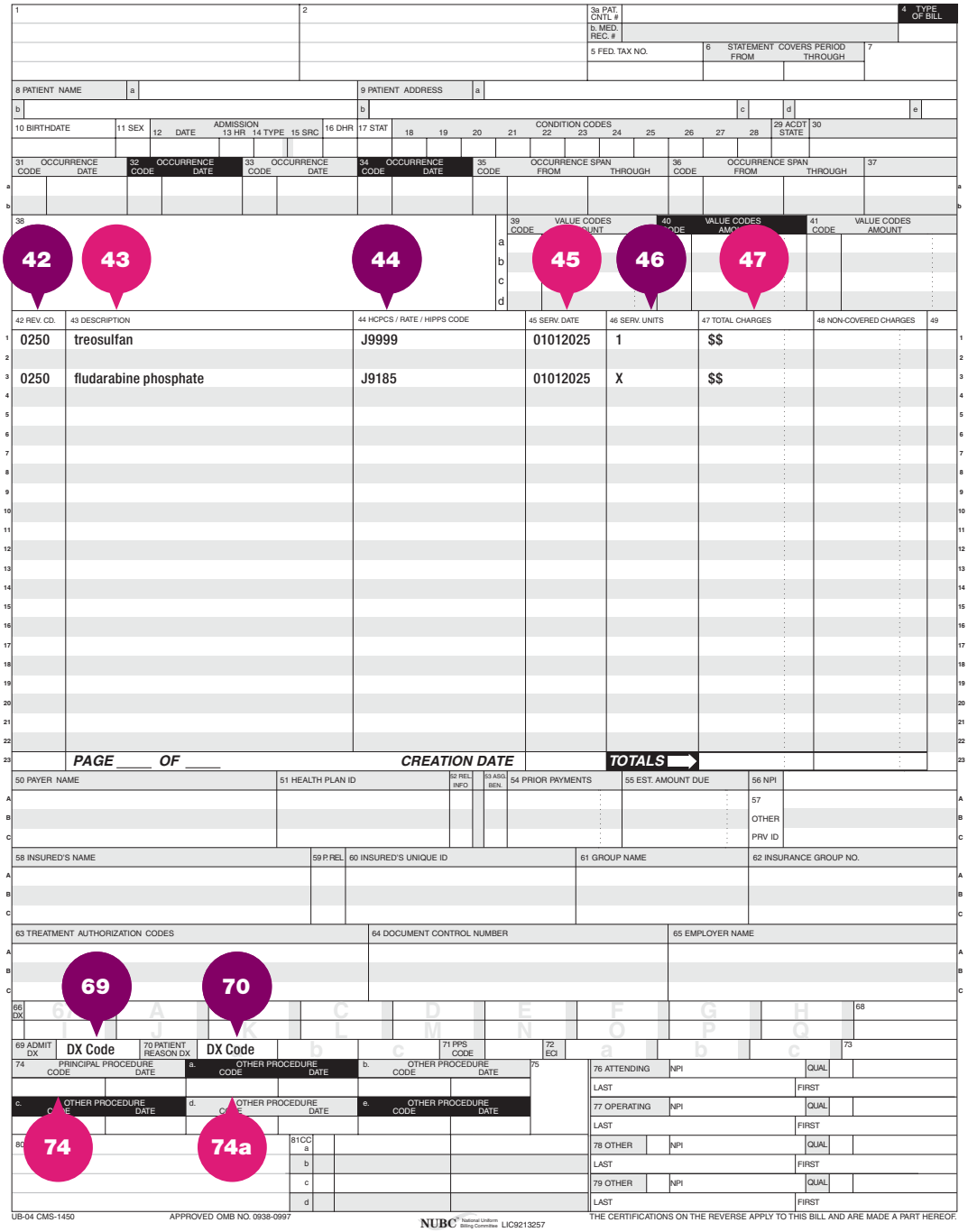

Image is illustrative only. Each payer may have unique guidance for claims completion and submission. Please consult with the payer to ensure compliance with their requirements.

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GRAFAPEX™ (treosulfan) for Injection

Sample Hospital Outpatient Claim Form: CMS-1450/UB-04[17,18]

Field Locator (FL) 42
Input appropriate revenue code for treosulfan (0636 – drugs requiring detailed coding), fludarabine phosphate (0250 – General pharmacy), and drug administration (0335 Chemotherapy administration – IV)

FL 43
Input description for drug and drug administration, for treosulfan and fludarabine phosphate, include N4-qualifier annotated 11-digit National Drug Codes [NDCs] with appropriate unit of measure designation and dose delivered

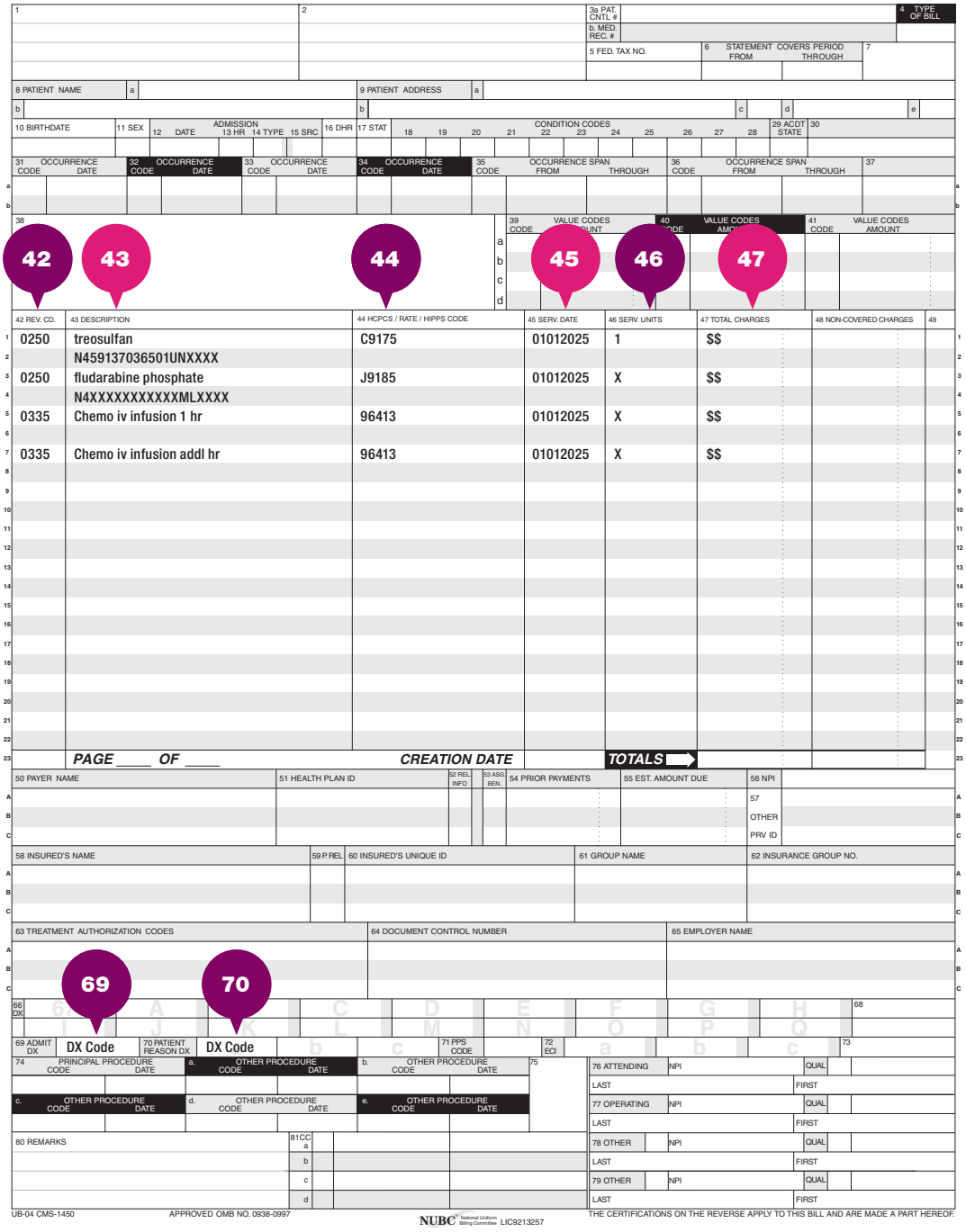
FL 44
Input HCPCS code such as C9175 Injection, treosulfan, 50 mg and J9185 Injection, fludarabine phosphate, 50 mg

FL 45
Input date of service (MMDDYYYY)

FL 46
Input service units

FL 47
Input total charges

FL 69-70
Input diagnosis (Dx) codes



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0250	treosulfan	C9175	01012025	1	$$	
	N459137036501UNXXXX					
0250	fludarabine phosphate	J9185	01012025	X	$$	
	N4XXXXXXXXXXXMLXXXX					
0335	Chemo iv infusion 1 hr	96413	01012025	X	$$	
0335	Chemo iv infusion addl hr	96413	01012025	X	$$	

PAGE ____ OF ____ CREATION DATE TOTALS

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Image is illustrative only. Each payer may have unique guidance for claims completion and submission. Please consult with the payer to ensure compliance with their requirements.

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PRODUCT INFORMATION[1]

GRAFAPEX™ (treosulfan) for Injection

How Supplied

GRAFAPEX (treosulfan) for Injection is a white, sterile, lyophilized powder for reconstitution. It is supplied in a carton containing one single-dose vial. See Table 1: How Supplied for reference.

Providers should utilize information provided in Table 2: Reconstitution Solution Volume to establish required dosing and final concentration of GRAFAPEX. This information will then support appropriate coding and billing requirements.

Table 1: How Supplied

Strength	NDC
1 g/vial	59137-335-01
5 g/vial	59137-365-01

Table 2: Reconstitution Solution Volume

Strength	Volume
1 g/vial	20 ML
5 g/vial	100 ML

Storage and Handling

If not used immediately, store reconstituted GRAFAPEX solution at room temperature 20°C to 25°C (68°F to 77°F) for up to 24 hours. Do not use if the solution contains a precipitate. **Do not refrigerate.**

Infuse GRAFAPEX intravenously over 2 hours. Confirm patency of the intravenous line prior to infusion. Monitor for extravasation; if extravasation occurs, stop the infusion.

For more information, including ordering details and Full Prescribing Information, including boxed warning, please visit: https://www.GRAFAPEX.com.

Healthcare Professional and Patient Access, Reimbursement, and Financial Support Services

Benefit Investigations

CORE Connections conducts benefits investigations to determine GRAFAPEX patient-specific insurance coverage, precertification or prior authorization requirements, and out-of-pocket costs (copay, coinsurance, deductible)

Precertification, Prior Authorization, and Appeal Support

CORE Connections reduces the administrative burden and accelerates patient access to GRAFAPEX by assisting HCPs with insurance precertifications, prior authorizations, and denial appeals. This may include providing Insurance precertification and prior authorization forms, medical policies, medical necessity forms, and appeal policies and procedures

Billing & Coding Support

CORE Connections assists HCPs with billing and coding questions or issues related to GRAFAPEX (e.g. ICD-10, CPT, and HCPCS codes)

Coupon Program

CORE Connections provides a coupon program for commercially insured patients that may reduce patient out-of-pocket costs associated with GRAFAPEX such as copay, coinsurance, and deductible

Patient Assistance Program

CORE Connections provides GRAFAPEX free of charge for uninsured patients who demonstrate qualifying financial need

Charitable Foundation Referrals

CORE Connections refers patients to charitable foundations that match their specific needs and may assist with costs such as copay, coinsurance, deductible, medical travel expenses, and other treatment-related costs

CORE CONNECTIONS
Coverage, Resources and Education

Patient Assistance Program

Reach out for more information on how CORE Connections can support your patients

9:00 am to 6:00 pm EST Monday through Friday (excluding holidays)

Email coreconnectionscare@pharmacord.com **Call** 1-84-GRAFAPEX (844-723-2739)

CALL CORE CONNECTIONS 1-84-GRAFAPEX (1-844-723-2739)

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MP-TREO-0109 July 2025

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