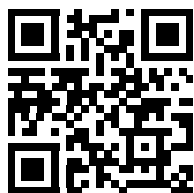# DIGIFab®

digoxin immune fab (ovine)

Coding Guide

Full Prescribing Information

Diagnostic and Billing Codes

DIGIFab® Digoxin Immune Fab (Ovine) is reimbursed through the Medicare Part A benefit as part of the diagnosis-related group (DRG) payment weight in the Inpatient Prospective Payment System payment equation. Medicaid reimbursement will vary by state. Specific benefit coverage varies by payor and provider contract.

ICD-10-CM Diagnosis Codes

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) is a morbidity classification published by the United States for classifying diagnoses and reason for visits in all healthcare settings. ICD-10-CM codes are used in inpatient, outpatient, and office settings. Patients are assigned both principle and secondary diagnoses. The principle diagnosis is the condition chiefly responsible for the patient's admission. Secondary diagnoses are conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Only diagnoses that are monitored, evaluated, or treated should be documented. The treating physician is responsible for selecting the ICD-10-CM code that best describes the patient's condition and supports the medical record.

ICD-10-CM codes are seven-character, alphanumeric codes. Each code begins with a letter, and that letter is followed by two numbers. The first three characters of ICD-10-CM are the "category." The category describes the general type of injury or disease. The category is followed by a decimal point and the subcategory. This is followed by up to two subclassifications, which further explain the cause, manifestation, location, severity, and type of injury or disease. The last character is the extension. The extension describes the type of encounter this is (e.g., initial, subsequent, or sequela).

ICD-10-CM Code	Descriptor
T46.0 - - -	Poisoning by, adverse effect of and underdosing of cardiac-stimulant glycosides and drugs of similar action
T46.1 - - -	Poisoning by, adverse effect of and underdosing of calcium-channel blockers
T46.2 - - -	Poisoning by, adverse effect of and underdosing of other antidysrhythmic drugs, not elsewhere classified
T46.3 - - -	Poisoning by, adverse effect of and underdosing of coronary vasodilators
T50.913A	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, initial encounter

The last three characters may be specified to indicate if the event was unintentional (accidental) vs intentional; self-harm vs assault; initial vs subsequent vs sequela. Coders should code to the highest specificity possible.

HCPCS, DRG, and Revenue Codes

The HCPCS (Healthcare Common Procedure Coding System), DRG, and revenue codes provided are based on CMS guidelines.

The following is the HCPCS code for DIGIFab.	
HCPCS Code	**Description**
J1162	Injection, digoxin immune fab (ovine), per vial

Patients requiring DIGIFab may present with a range of medical conditions, thereby increasing the variability of applicable DRG codes. The following are possible DRG codes that a patient receiving DIGIFab may be assigned.	
DRG Code	**Description**
291	Heart failure and shock with major complications/comorbidity (MCC)
292	Heart failure and shock with complications/comorbidity (CC)
293	Heart failure and shock without CC/MCC
917	Poisoning and toxic effect of drugs with MCC
918	Poisoning and toxic effect of drugs without MCC

The following are possible revenue codes to support a hospital claim.	
Revenue Code	**Description**
0450	Emergency department visit
0636	Drugs requiring detailed coding

DIGIFab is supplied as a sterile, lyophilized preparation. Each vial contains 40 mg of digoxin immune Fab protein, contains no preservatives, and is intended for one time use. Each carton contains 1 vial of DigiFab.[1]

NDC#: 50633-120-11

DIGIFab®
digoxin immune fab (ovine)

Health Insurance Claim Form

1			2			3a PAT. CNTL #		4 TYPE OF BILL
						b. MED. REC. #		
						5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM THROUGH	7

8 PATIENT NAME	a	9 PATIENT ADDRESS	a			c	d	e
b		b						

| 10 BIRTHDATE | 11 SEX | 12 DATE | ADMISSION 13 HR 14 TYPE 15 SRC | 16 DHR | 17 STAT | 18 19 20 21 | CONDITION CODES 22 23 24 25 26 27 28 | 29 ACDT STATE | 30 |

31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE SPAN CODE FROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37
a						a
b						b

38		39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT
		a		
		b		
		c		
		d		

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1							1
2							2
3							3

Field 42: Enter appropriate revenue code

Field 43: Enter NDC# 50633012011 with no hyphens or spaces

PAGE _____ OF _____   CREATION DATE   TOTALS ➡

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
A							57
B							OTHER
C							PRV ID

58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A				
B				
C				

Field 67: Enter appropriate ICD-10-CM diagnosis code

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A		
B		
C		

Field 71: Enter appropriate DRG code

66 DX	67 A B C D E F G H	68
	I J K L M N O P Q	

| 69 ADMIT DX | 70 PATIENT REASON DX a b c | 71 PPS CODE | 72 ECI a b c | 73 |

74 PRINCIPAL PROCEDURE CODE DATE	a. OTHER PROCEDURE CODE DATE	b. OTHER PROCEDURE CODE DATE	75	76 ATTENDING NPI QUAL
				LAST FIRST
c. OTHER PROCEDURE CODE DATE	d. OTHER PROCEDURE CODE DATE	e. OTHER PROCEDURE CODE DATE		77 OPERATING NPI QUAL
				LAST FIRST
	81CC a			78 OTHER NPI QUAL
	b			LAST FIRST
	c			79 OTHER NPI QUAL
	d			LAST FIRST

Field 74: Enter appropriate ICD-10-PCS code

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

DIGIFab ®
digoxin immune fab (ovine)

INDICATIONS AND USAGE

DIGIFab is indicated for the treatment of patients with life-threatening or potentially life-threatening digoxin toxicity or overdose, including:

- Known suicidal or accidental consumption of fatal doses of digoxin: 10 mg or more of digoxin in healthy adults, or 4 mg (or more than 0.1 mg/kg) in healthy children, or ingestion of an amount that can cause steady-state serum concentrations of ≥10 ng/mL;
- Chronic ingestions causing steady-state serum digoxin concentrations >6 ng/mL in adults or 4 ng/mL in children;
- Manifestations of life-threatening toxicity of digoxin overdose such as severe ventricular arrhythmias, progressive bradycardia, and second or third degree heart block not responsive to atropine, serum potassium levels exceeding 5.5 mEq/L in adults or 6 mEq/L in children with rapidly progressive signs and symptoms of digoxin toxicity.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

General

Suicidal ingestion may result from more than one drug. Consider toxic effects of other drugs or poisons in cases where signs and symptoms of digitalis toxicity are not relieved by administration of DIGIFab.

Rapid drop in serum potassium concentration may occur after treatment. Monitor frequently.

Patients with poor cardiac function may deteriorate secondary to the withdrawal of the inotropic action of digoxin by DIGIFab. Monitor frequently and provide additional inotropic support if needed. Postpone re-digitalization, if possible, until the Fab fragments have been eliminated; this may require several days or a week or longer in patients with impaired renal function.

Hypersensitivity Reactions

Anaphylaxis and hypersensitivity reactions are possible. Carefully monitor patients for signs and symptoms of an acute allergic reaction and if one occurs, stop the infusion and treat immediately with appropriate emergency medical care.

Patients with known allergies to sheep protein or those who have previously received intact ovine antibodies or Fab are particularly at risk for an anaphylactic reaction.

Do not administer DIGIFab to patients with a known history of hypersensitivity to papaya or papain unless the benefits outweigh the risks and appropriate management for anaphylactic reactions is readily available.

Use of DIGIFab in Renal Failure

The elimination half-life of DIGIFab in renal failure has not been clearly defined. Monitor patients with severe renal failure who receive DIGIFab for a prolonged period for possible recurrence of toxicity. Monitoring of free (unbound) digoxin concentrations after the administration may be appropriate

Laboratory Tests

DIGIFab may interfere with digitalis immunoassay measurements. Thus, standard serum digoxin concentration measurements may be clinically misleading until the Fab fragments are eliminated from the body. This may take several days or a week or more in patients with markedly impaired renal function. If possible, obtain serum digoxin samples before DIGIFab administration to establish the level of serum digoxin at the time of diagnosis.

The total serum digoxin concentration may rise precipitously following administration of DIGIFab, but this will be almost entirely bound to the Fab fragment and not able to react with receptors in the body.

Adverse Reactions

The most common adverse reactions (>7%) related to DIGIFab administration are worsening congestive heart failure (13%), hypokalemia (13%), and worsening atrial fibrillation (7%).

Reference: 1. DIGIFab Digoxin Immune Fab (ovine). Package insert. BTG International Inc.; 2017.

Full Prescribing Information