# SAMPLE CODING AND BILLING FOR ACTIVASE® (ALTEPLASE)

# Tips and considerations for inpatient and outpatient claims submission

## **Indications**

Activase<sup>®</sup> (alteplase) is indicated for the treatment of acute ischemic stroke. Exclude intracranial hemorrhage as the primary cause of stroke signs and symptoms prior to initiation of treatment. Initiate treatment as soon as possible but within 3 hours after symptom onset.

Activase is indicated for use in acute myocardial infarction (AMI) for the reduction of mortality and reduction of the incidence of heart failure.

<u>Limitation of Use:</u> The risk of stroke may outweigh the benefit produced by thrombolytic therapy in patients whose AMI puts them at low risk for death or heart failure.

Activase is indicated for the lysis of acute massive pulmonary embolism (PE), defined as:

- Acute pulmonary emboli obstructing blood flow to a lobe or multiple lung segments.
- Acute pulmonary emboli accompanied by unstable hemodynamics, e.g., failure to maintain blood pressure without supportive measures.

#### **Important Safety Information**

#### Contraindications

Do not administer Activase to treat acute ischemic stroke in the following situations in which the risk of bleeding is greater than the potential benefit: current intracranial hemorrhage (ICH); subarachnoid hemorrhage; active internal bleeding; recent (within 3 months) intracranial or intraspinal surgery or serious head trauma; presence of intracranial conditions that may increase the risk of bleeding (e.g., some neoplasms, arteriovenous malformations, or aneurysms); bleeding diathesis; and current severe uncontrolled hypertension.

Do not administer Activase to treat acute myocardial infarction or pulmonary embolism in the following situations in which the risk of bleeding is greater than the potential benefit: active internal bleeding; history of recent stroke; recent (within 3 months) intracranial or intraspinal surgery or serious head trauma; presence of intracranial conditions that may increase the risk of bleeding; bleeding diathesis; and current severe uncontrolled hypertension.

Please see additional Important Safety Information on the last page and the full <u>Prescribing Information</u>.

**ACTIVASE ALTEPLASE** A RECOMBINANT TISSUE PLASMINOGEN ACTIVATOR

# What's unique about coding and billing for Activase<sup>®</sup> (alteplase)?

# When submitting claims for Activase, it is important to keep a few considerations in mind.

Some of these are unique to Activase, while others are common to all infused products. This guide will go over these considerations in detail.

Please note that this guide focuses on Medicare payment methodologies. Private payers may employ different coding and reimbursement methodologies. Please contact individual private payers as needed to clarify their specific coding and reimbursement policies.

Correct coding is the responsibility of the provider and Genentech does not make any representation or guarantee concerning reimbursement or coverage.



## Inpatient hospital: admitted to the hospital for care

Reimbursement for all services, drugs and supplies administered to Medicare beneficiaries during a single inpatient hospitalization is bundled into a single prospective payment amount. This payment amount is determined by the MS-DRG<sup>1</sup> system, which classifies patients into clinically cohesive groups with similar hospital resource use and length of stay. The MS-DRG assignment for each case is based on the ICD-10<sup>2</sup> diagnosis and procedure codes reported on the claim form.

Under the MS-DRG system, Activase is not separately reimbursable when administered to Medicare beneficiaries in the inpatient setting. Instead, its cost is intended to be covered by the single MS-DRG payment. To ensure appropriate reimbursement, be sure to accurately code for all patient diagnoses and procedures performed.

Private payers may employ different reimbursement methodologies that may or may not allow for the separate reimbursement of Activase when administered in the inpatient setting. Some payers may require additional coding and patient-specific clinical information to determine coverage and payment for the inpatient stay. Please contact individual private payers to clarify their specific reimbursement policies for Activase.



# **Outpatient hospital:** in the emergency room for treatment or undergoing tests but not admitted to the hospital

During outpatient encounters, hospitals use the ICD-10<sup>2</sup> code sets to report medical diagnoses and HCPCS<sup>3</sup> Level II codes and American Medical Association (AMA) CPT<sup>®4</sup> to report materials and procedures provided.

<sup>1</sup>MS-DRG=Medicare Severity Diagnosis Related Group; <sup>2</sup>ICD-10=International Classification of Diseases, 10th Revision; <sup>3</sup>HCPCS=Healthcare Common Procedure Coding System; <sup>4</sup>CPT=Current Procedural Terminology; <sup>5</sup>ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; <sup>6</sup>ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; <sup>7</sup>NDC=National Drug Code.

## Codes in the inpatient and outpatient settings of care

	Inpatient	Outpatient
ICD-10-CM⁵		
ICD-10-PCS <sup>6</sup>		
HCPCS (J-code)		
СРТ		
MS-DRG		
NDC <sup>7</sup>		

## Considerations for Activase® (alteplase) clinical documentation

Lack of sufficient clinical documentation is often a key factor leading to claims denials and reimbursement issues. The ICD-10 stroke codes are very specific and therefore require very specific clinical documentation. As such, below are some tips for your consideration.



Provide clear and concise documentation. Explicitly document findings to support diagnosis of acute stroke and subsequent sequelae of stroke using diagnostic statements that are compatible with ICD-10 nomenclature



Focus clinical documentation on the specific type of stroke, artery affected and laterality. Providers can also specify occlusions or stenosis to an artery and laterality



It is important to document comorbid conditions and any planned or expected procedures



Non-specific codes should not be used when the cause/site of the occlusion is known



A joint effort between the healthcare provider, stroke team, coder and biller is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. Through this joint effort, your team may be better able to identify any clinical documentation that may be missing

## Example coding scenarios

### Scenario 1: Treat and admit



**The patient arrives** with symptoms of an acute ischemic stroke (AIS) and can be treated within 3 hours after symptom onset.



Activase<sup>®</sup> (alteplase) is administered in the emergency department and the patient is admitted for care in the hospital.

### Potential codes in this scenario

**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes



For hospital inpatient procedure coding, use appropriate ICD-10-PCS codes



## For the reimbursement of all services,

supplies and drugs furnished to a Medicare beneficiary during an inpatient hospitalization, use appropriate MS-DRG codes



For physician procedure coding,\*

use appropriate CPT codes

\*Note: Additional evaluation and management codes will be determined by services provided.

These scenarios are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.



**The patient arrives** with symptoms of an acute ischemic stroke (AIS) and can be treated within 3 hours after symptom onset. T Activase<sup>®</sup> (alteplase) is administered in the emergency department.



The patient is then transferred

to another hospital for inpatient admission (often referred to as "drip and ship").

## Potential codes in this scenario

#### Shipping hospital (outpatient)



**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes



**For the product code,** use appropriate HCPCS code (J-code)



For physician procedure coding,\* use appropriate CPT codes

#### **Receiving hospital (inpatient)**



**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes and Z-code



#### For the reimbursement of all services,

supplies and drugs furnished to a Medicare beneficiary during an inpatient hospitalization, use appropriate non-thrombolytic MS-DRG codes

# Example coding scenarios (cont)

## Scenario 3: Stroke treated; no stroke on follow-up imaging



**The patient arrives** with symptoms of an acute ischemic stroke (AIS) and can be treated within 3 hours after symptom onset.



Activase<sup>®</sup> (alteplase) is administered in the emergency department and the patient is admitted for care in the hospital.



On follow-up imaging, no stroke detected.

## Potential codes in this scenario



**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes



**For hospital inpatient procedure coding,** use appropriate ICD-10-PCS codes



**For the reimbursement of all services,** supplies and drugs furnished to a Medicare beneficiary during an inpatient hospitalization, use appropriate MS-DRG codes



For physician procedure coding,\* use appropriate CPT codes

For additional CMS coding guidance, please refer to pages 38019–38022 in the August 2017 *Federal Register*. 2017;82(155):37990-38589. https://www.govinfo.gov/content/pkg/FR-2017-08-14/pdf/2017-16434.pdf. Accessed October 25, 2022.

\*Note: Additional evaluation and management codes will be determined by services provided.

These scenarios are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

## Scenario 4: Mechanical thrombectomy



**The patient arrives** with symptoms of an acute ischemic stroke (AIS) and can be treated within 3 hours after symptom onset.



Activase<sup>®</sup> (alteplase) is administered in the emergency department and the patient is admitted for care in the hospital.



The patient then undergoes mechanical thrombectomy.

## Potential codes in this scenario



**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes



For hospital inpatient procedure coding, use appropriate ICD-10-PCS codes



For the reimbursement of mechanical thrombectomy and Activase, use appropriate MS-DRG codes



For physician procedure coding,\* use appropriate CPT codes

# Example coding scenarios (cont)

## Scenario 5: Inpatient stroke



#### The patient is admitted to the hospital as an

**inpatient.** The patient has symptoms of an acute ischemic stroke (AIS) and can be treated while in the hospital for care.



Activase<sup>®</sup> (alteplase) is administered to the patient in the hospital.

## Potential codes in this scenario



**For diagnosis coding,** use appropriate ICD-10-CM diagnosis codes



**For hospital inpatient procedure coding,** use appropriate ICD-10-PCS codes



**For the reimbursement of all services,** supplies and drugs furnished to a Medicare beneficiary during an inpatient hospitalization, use appropriate MS-DRG codes



For physician procedure coding,\*

use appropriate CPT codes

\*Note: Additional evaluation and management codes will be determined by services provided.

These scenarios are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

## Scenario 6: Telestroke



**The patient arrives** with symptoms of an acute ischemic stroke (AIS) and can be treated within 3 hours after symptom onset.



Activase<sup>®</sup> (alteplase) is administered in a community hospital facility after consultation with a specialist from a stroke center and the patient is admitted for care in the hospital.

### Potential codes in this scenario

**Distant site** (The telemedicine site where the medical provider or specialist is seeing the patient at a distance or consulting with the patient's provider)



The specialist providing consultation

would use appropriate HCPCS and place of service codes

**Originating site** (The site where the patient and the patient's provider is physically located)



**The originating site providing the general services** would use appropriate telehealth HCPCS code (J-code)



For diagnosis coding, use appropriate ICD-10-CM diagnosis codes



61)

For hospital inpatient procedure coding, use appropriate ICD-10-PCS codes

#### For the reimbursement of all services,

supplies and drugs furnished to a Medicare beneficiary during an inpatient hospitalization, use appropriate MS-DRG codes

**For physician procedure coding,**\* use appropriate CPT codes

#### **ICD-10-CM Diagnosis Codes**

ICD-10-CM codes are used by both physicians and hospitals to classify medical diagnoses and conditions, and support medical necessity for specific procedures and services.

#### Acute Ischemic Stroke (AIS) codes for precerebral arteries

Code	Description	(-) Add 5th character	(-) Add 6th character (when applicable)
163.0 -	Cerebral infarction due to <b>thrombosis</b> of precerebral arteries	0 – unspecified	1 – right artony
<b>I63.1</b> -	Cerebral infarction due to <b>embolism</b> of precerebral arteries	<ul> <li>precerebral artery</li> <li>1 - right artery</li> <li>2 - basilar artery</li> <li>2 - basilar artery</li> <li>3 - bilateral arteries</li> <li>4 - right artery</li> <li>5 - bilateral arteries</li> </ul>	
163.2 -	Cerebral infarction due to <b>unspecified</b> occlusion or stenosis of precerebral arteries	3 – carotid artery 9 – other precerebral artery	9 – unspecified artery

#### AIS codes for cerebral arteries

Code	Description	(-) Add 5th character	(-) Add 6th character (when applicable)
<b>I63.3</b> -	Cerebral infarction due to <b>thrombosis</b> of cerebral arteries	teriesartery1 - middle cerebral artery1 - right arteryfarction due to <b>embolism</b> 2 - anterior cerebral artery2 - left arteryarteries3 - posterior cerebral3 - bilateral arteries	
<b>I63.4</b> -	Cerebral infarction due to <b>embolism</b> of cerebral arteries		
<b>I63.5</b> -	Cerebral infarction due to <b>unspecified</b> occlusion or stenosis of cerebral arteries	artery 4 – cerebellar artery 9 – other cerebral artery	9 – unspecified artery

#### History of IV tPA

Code	Description
Z92.82	Status post administration of IV tPA in a different facility within the last 24 hours prior to admission to current facility

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

#### Additional codes that map to MS-DRG 061, 062 and 063 when a thrombolytic is used

Code	Description (-) Add 5th		
163.6	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic		
163.81	Other cerebral infarction due to occlusion or stenosis of small artery		
163.89	Other cerebral infarction		
163.9	Cerebral infarction, unspecified		
165.0 -	Occlusion and stenosis of vertebral arteries       1 - right artery         2 - left artery       3 - bilateral arteries         9 - unspecified arter		
165.1	Occlusion and stenosis of basilar artery		
165.2 -	Occlusion and stenosis of carotid arteries	1 – right artery 2 – left artery 3 – bilateral arteries 9 – unspecified artery	
165.8	Occlusion and stenosis of other precerebral arteries		
165.9	Occlusion and stenosis of unspecified precerebral artery		
166.0 -	Occlusion and stenosis of middle cerebral arteries	1 – right artery	
166.1 -	Occlusion and stenosis of anterior cerebral arteries 2 – left arteria 3 – bilateral a		
166.2 -	Occlusion and stenosis of posterior cerebral arteries	9 – unspecified artery	
166.3	Occlusion and stenosis of cerebellar arteries		
166.8	Occlusion and stenosis of other cerebral arteries		
166.9	Occlusion and stenosis of unspecified cerebral artery		
167.81	Acute cerebrovascular insufficiency		
167.82	Cerebral ischemia		
167.841	Reversible cerebrovascular vasoconstriction syndrome		
G45.0	Vertebro-basilar artery syndrome		
G45.1	Carotid artery syndrome (hemispheric)		
G45.2	Multiple and bilateral precerebral artery syndromes		
G45.8	Other transient cerebral ischemic attacks and related syndromes		
G45.9	Transient cerebral ischemic attack, unspecified		
G46.0	Middle cerebral artery syndrome		
G46.1	Anterior cerebral artery syndrome		
G46.2	Posterior cerebral artery syndrome		

Please see Important Safety Information on the first and last pages and the full <u>Prescribing Information</u>.

For additional CMS discussion on assignment of DRGs and codes in ischemic stroke, please see "Precerebral Occlusion or Transient Ischemic Attack with Thrombolytic" in the August 2017 *Federal Register*. 2017;82(155):37990-38589. <u>https://www.govinfo.gov/content/pkg/FR-2017-08-14/pdf/2017-16434.pdf</u>. Accessed October 25, 2022.

#### **Acute Myocardial Infarction (AMI)**

Code	Description	(-) Add 4th character	(-) Add 5th character
I21.0 -	ST elevation (STEMI) myocardial infarction of anterior wall		<ol> <li>Involving left main coronary artery</li> <li>Involving left anterior descending coronary artery</li> <li>Involving other coronary artery</li> </ol>
l21.1 -	ST elevation (STEMI) myocardial infarction of inferior wall		1 – Involving right coronary artery 9 – Involving other coronary artery
l21.2 -	.2 - ST elevation (ST EIVII) myocardial coronary a		<ol> <li>1 – Involving left circumflex coronary artery</li> <li>9 – Involving other sites</li> </ol>
l21.3	ST elevation (STEMI) myocardial infarction of unspecified site		
<b>I21.4</b>	Non-ST elevation (NSTEMI) myocardial infarction		
I21.9	Acute myocardial infarction, unspecified		
I21.A1	Myocardial infarction type 2		
l21.A9	Other myocardial infarction type		
122	<ul> <li>Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction</li> <li>O – STEMI of anterior wall 1 – STEMI of inferior wall 2 – NSTEMI 8 – STEMI of other sites 9 – STEMI of unspecified site</li> </ul>		

Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.



Code	Description	
126.02	Saddle embolus of pulmonary artery with acute cor pulmonale	
126.09	Other pulmonary embolism with acute cor pulmonale	
126.92	Saddle embolus of pulmonary artery without acute cor pulmonale	
126.99	Other pulmonary embolism without acute cor pulmonale	

## Sample hospital inpatient procedure coding

ICD-10-PCS codes are used by hospitals to report procedures performed in the inpatient setting.

Code	Description	
3E03017	Introduction of other thrombolytic into peripheral vein, open approach	
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach	
3E04017	Introduction of other thrombolytic into central vein, open approach	
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach	
3E05017	Introduction of other thrombolytic into peripheral artery, open approach	
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach	
3E06017	Introduction of other thrombolytic into central artery, open approach	
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach	
3E08017	Introduction of other thrombolytic into heart, open approach	
3E08317	Introduction of other thrombolytic into heart, percutaneous approach	

## Sample hospital inpatient MS-DRGs

Under the MS-DRG system for hospital inpatient payment, each inpatient stay is assigned to a diagnosis-related group. This is based on the combination of ICD-10-CM diagnosis and procedure codes. Each MS-DRG has a relative weight that is then converted to a flat payment amount. Only 1 MS-DRG is assigned for each inpatient stay, regardless of the number of procedures performed.

#### Acute Ischemic Stroke (AIS)

Code	Description		
I	Ischemic stroke with removal of thrombus (Mechanical thrombectomy $\pm$ tPA)		
023	Craniotomy with major device implant or acute complex central nervous system principal diagnosis with a major complication or comorbidity (MCC) or chemotherapy implant, or epilepsy with neurostimulator		
024	Craniotomy with major device implant or acute complex central nervous system principal diagnosis without a major complication or comorbidity (MCC)		
	Ischemic stroke with administration of thrombolytic only		
061	lschemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with a major complication or comorbidity (MCC)		
062	Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with a complication or comorbidity (CC)		
063	Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent without a complication or comorbidity (CC)/major complication or comorbidity (MCC)		
Ischemic stroke with administration of thrombolytic only			
065	Intracranial hemorrhage or cerebral infarction with CC or TPA in 24 hours		

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

#### Pulmonary Embolism (PE)

Code	Description
175	Pulmonary embolism with a major complication or comorbidity (MCC), or acute cor pulmonale
176	Pulmonary embolism without a major complication or comorbidity (MCC)

#### Acute Myocardial Infarction (AMI)

Code	Description	
280	Acute myocardial infarction, discharged alive with a major complication or comorbidity (MCC)	
281	Acute myocardial infarction, discharged alive with a complication or comorbidity (CC)	
282	Acute myocardial infarction, discharged alive without a complication or comorbidity (CC)/ major complication or comorbidity (MCC)	
283	Acute myocardial infarction, expired with a major complication or comorbidity (MCC)	
284	Acute myocardial infarction, expired with a complication or comorbidity (CC)	
285	Acute myocardial infarction, expired without a complication or comorbidity (CC)/major complication or comorbidity (MCC)	

# Physician procedure coding and product coding for Activase<sup>®</sup> (alteplase)

HCPCS codes beginning with the letter "J" are used for products, supplies and services administered in the outpatient setting.

NDCs are universal product identifiers assigned to drugs upon FDA approval.

Product Codes				
HCPCS (J-code)	J2997		Injection, alteplase recombinant, 1 mg	
NDC	10-digit	50242-044-13	50 mL in 1 vial, single use	
	11-digit	50242-0044-13	50 mL in 1 vial, single use	
	10-digit	50242-085-27	100 mL in 1 vial, single use	
	11-digit	50242-0085-27	100 mL in 1 vial, single use	

CPT is a list of descriptive terms and codes for providers to report medical procedures and professional services.

Administration of Thrombolytic (IV tPA)						
СРТ	37195	Thrombolysis, cerebral, by intravenous infusion				
	92977	Thrombolysis, coronary, by intravenous infusion				
	61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacologic thrombolytic injection(s)				

FDA=US Food and Drug Administration.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the professional submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

# Telehealth

#### **Telehealth Codes for Professional Fees at Distant Site**

Administration of thrombolytic (IV tPA)				
HCPCS	G0425		Telehealth consultations, emergency department or initial inpatient, 30 minutes	
	G0426		Telehealth consultations, emergency department or initial inpatient, 50 minutes	
	G0427		Telehealth consultations, emergency department or initial inpatient, 70 minutes	
	G0508		Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth	
	G	)509	Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth	
HCPCS	GQ		Services delivered via asynchronous telecommunications system Applicable only for federal demonstration projects conducted in Alaska and Hawaii. To be used with HCPCS codes G0425 through G0427	
Modifiers	GT		Services delivered via interactive video and video telecommunications systems Applicable only for distant site practitioners billing under Critical Access Hospital (CAH) Method II. To be used with HCPCS codes G0425 through G0427	
Place of	Code	Name	The location where health services and health-	
Service	02	Telehealth	related services are provided or received, through a telecommunication system	

Telehealth Code for Originating Site Facility Fee					
HCPCS	Q3014	Telehealth originating site facility fee			

## Important Safety Information (cont)

#### **Warnings and Precautions**

#### Bleeding

Activase can cause significant, sometimes fatal internal or external bleeding. Avoid intramuscular injections and trauma to the patient. Perform venipunctures carefully and only as required. Fatal cases of hemorrhage associated with traumatic intubation in patients administered Activase have been reported. Heparin, aspirin, or Activase may cause bleeding complications; therefore, carefully monitor for bleeding. If serious bleeding occurs, terminate the Activase infusion, and treat properly.

#### Hypersensitivity

Hypersensitivity, including urticarial / anaphylactic reactions, have been reported. Rare fatal outcome for hypersensitivity was reported. Angioedema has been observed during and up to 2 hours after Activase infusion in patients treated for acute ischemic stroke and acute myocardial infarction. In many cases, patients received concomitant angiotensin-converting enzyme inhibitors. Monitor patients treated with Activase during and for several hours after infusion for hypersensitivity. If signs of hypersensitivity occur, e.g. anaphylactoid reaction or angioedema develops, discontinue the Activase infusion and promptly institute appropriate therapy (e.g., antihistamines, intravenous corticosteroids, epinephrine).

#### Thromboembolism

The use of thrombolytics can increase the risk of thrombo-embolic events in patients with high likelihood of left heart thrombus, such as patients with mitral stenosis or atrial fibrillation. Activase has not been shown to treat adequately underlying deep vein thrombosis in patients with PE. Consider the possible risk of re-embolization due to the lysis of underlying deep venous thrombi in this setting.

#### **Cholesterol Embolization**

Cholesterol embolism, sometimes fatal, has been reported rarely in patients treated with thrombolytic agents.

#### **Coagulation Tests May be Unreliable during Activase Therapy**

Coagulation tests and/or measures of fibrinolytic activity may be unreliable during Activase therapy.

#### **Adverse Reactions**

The most frequent adverse reaction associated with Activase therapy is bleeding.

#### Please see the full <u>Prescribing Information</u> for additional Important Safety Information.

You may report side effects to the FDA at (800) FDA-1088 or <u>www.fda.gov/medwatch</u>. You may also report side effects to Genentech at (888) 835-2555.

For more information:



Visit ACTIVASE.com



**Contact** your Activase representative

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