Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1155(1)
Transmittal Sheet
June 2, 2018

TREATMENT OF ACUTE ISCHEMIC STROKE

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive updates VHA policy for management of Acute Ischemic Stroke (AIS).

2. SUMMARY OF MAJOR CHANGES:

- a. Amendment dated November 13, 2018, updates section 3.d., specifically the definition of VHA Supporting Stroke Facility; section 4. the policy statement; and section 6, Requirements for the Medical Facility AIS Management Plan, specifically: 6a.; 6.e; 6.h(2); 6.h.(3)(a); 6.h.(3)(b), 6.h.(4); 6.i; 6k; and section 7, References.
 - b. Major changes are as follows:
- (1) Paragraph 3.a.: Delineates requirements for an additional designation, the VHA Comprehensive Stroke Center.
- (2) Paragraph 5.e.(4): Emphasizes the responsibility of the Veterans Integrated Service Network (VISN) Directors to ensure facility compliance with the mandatory reporting of monthly stroke quality data for all levels of VA stroke centers and facilities.
- (3) Paragraph 6.h.: Identifies an additional quality indicator for endovascular intervention.
- (4) Paragraph 6.j: Clarifies the option to provide mandated clinical services by telemedicine.
- 3. RELATED ISSUES: None.
- **4. RESPONSIBLE OFFICE:** The Office of Specialty Care Services (10P11) is responsible for the content of this VHA directive. Questions may be referred to the National Director for Neurology at 202-461-7120.
- **5. RESCISSION:** VHA Directive 2011-038, dated November 2, 2011, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of June 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Carolyn Clancy, M.D. Executive in Charge

DISTRIBUTION: Emailed to the VHA Publications Distribution List on June 19, 2018.

CONTENTS

TREATMENT OF ACUTE ISCHEMIC STROKE

1.	PURPOSE	1
2.	BACKGROUND	1
3.	DEFINITIONS	1
4.	POLICY	2
5.	RESPONSIBILITIES	2
6.	REQUIREMENTS FOR THE MEDICAL FACILITY AIS MANAGEMENT PLAN	4
7	REFERENCES	5

TREATMENT OF ACUTE ISCHEMIC STROKE

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the management of acute ischemic stroke (AIS) in VA medical facilities. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

- a. Stroke is a leading cause of death or disability in the United States and the prevalence is projected to increase as the population ages. Strokes are classified as either hemorrhagic or ischemic. Acute ischemic stroke is caused by thrombosis or embolism and accounts for 85 percent of all strokes. VHA estimates that 15,000 Veterans are hospitalized each year for stroke. The VHA Quality Enhancement Research Initiative (QUERI) estimated the cost associated with new strokes as \$111 million for acute inpatient care, \$75 million for post-acute inpatient care, and \$88 million for follow-up care over 6 months subsequent to the stroke. Approximately 15 to 30 percent of stroke survivors are left with severe disability while 40 percent experience moderate functional impairments.
- b. VHA is committed to providing Veterans with access to emergency care that is prompt, safe, appropriate, and cost effective. Prompt access to care is crucial to limiting damage done by a stroke. Based upon the American Heart Association (AHA)/American Stroke Association (ASA) Guidelines (http://professional.heart.org/professional/GuidelinesStatements/UCM_316885_Guidelines-Statements.jsp) and supported by randomized controlled trial data, this directive systematizes and standardizes care provided to Veterans who experience an acute ischemic stroke. Stroke systems of care can address differences in site capabilities and improve the quality of care for Veterans, with the ultimate goal of reducing the morbidity and mortality associated with stroke.

3. **DEFINITIONS**

- a. <u>VHA Comprehensive Stroke Center.</u> A VHA Comprehensive Stroke Center (CSC) is a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose stroke patients emergently, including the administration of intravenous thrombolytic agents (recombinant tissue plasminogen activator (r-tPA), alteplase) and performance of surgical and interventional (endovascular) procedures, 24 hours a day, 7 days a week, 365 days a year.
- b. VHA Limited Hours Stroke Facility. A VHA Limited Hours Stroke Facility (LHSF) is a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of alteplase to appropriate candidates, during specified hours, as defined by local policy. Patients receiving thrombolytic medication may be admitted to the LHSF or transferred to a higher level of stroke care for admission, depending on clinical status.

- c. <u>VHA Primary Stroke Center.</u> A VHA Primary Stroke Center (PSC) is a facility or system with the necessary personnel, infrastructure, expertise, and programs to diagnose and treat stroke patients emergently, including the administration of recombinant alteplase to appropriate candidates, 24 hours a day, 7 days a week, 365 days a year in the Emergency Department (ED) or in the medical facility.
- d. <u>VHA Supporting Stroke Facility.</u> A VHA Supporting Stroke Facility (SSF) is a facility that does not have the necessary personnel, infrastructure, expertise, and programs to deliver consistent care of patients presenting with AIS, based on staffing, diagnostic services, or numbers/types of beds.

4. POLICY

It is VHA policy that all VA medical facilities providing inpatient acute care medical or surgical care, or inpatient chronic care and/or operating an emergency department (ED) or urgent care center (UCC) must have a written plan to provide appropriate care to patients with AIS. The plans are developed by local clinical leadership, with assistance and guidance from the Neurology Program Office and/or national TeleStroke Program when needed. Written plans must be reviewed by the Chief of Staff or designee at each medical facility on a regular basis and updated if necessary. NOTE: Example written plans are available on the VHA Neurology SharePoint (https://vaww.infoshare.va.gov/sites/MedicalSurgical/neurology/Documents/Forms/AllIte ms.aspx?RootFolder=%2Fsites%2FMedicalSurgical/%2Fneurology%2FDocuments%2F Stroke%2FFacility%20AIS%20Policy%2FPolicy%20Templates%20and%20Supplement atal%20Materials&FolderCTID=0x012000FE6140A70CFD9E46901B4A8414E940BB&V iew=%7B77238B88%2D5378%2D4E91%2D8DC7%2D96B0C7EA9B0D%7D).

5. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Deputy Under Secretary for Health for Policy and Services.</u> The Deputy Under Secretary for Health for Policy and Services is responsible for ensuring implementation and adherence with the requirements of this directive.
- c. <u>Chief Officer, Office of Specialty Care Services.</u> The Chief Officer is responsible for:
 - (1) Disseminating this directive to the VISN offices:
 - (2) Developing and maintaining stroke plans;
- (3) Working with VHA Clinical Operations (10NC) to ensure that all eligible Veterans with AIS have access to high quality specialized care.
 - (4) Reviewing and approving each VISN AIS care plan.

- d. **National Director for Neurology.** The National Director for Neurology is responsible for:
- (1) Developing and providing national guidance to the VISNs and medical facilities to ensure a standardized evaluation and management of patients with AIS presenting to the ED/Urgent Care Center (UCC) or in-hospital.
- (2) Identifying appropriate measures to assess stroke care quality and to quantify improvements in care, and to monitor compliance with reporting of stroke measures. See paragraph f.(1)(h) for methods to capture the quality indicators.
- e. <u>Veterans Integrated Service Network (VISN) Director.</u> Each VISN Director or designee is responsible for:
- (1) Assessing the capability of each medical facility in the VISN and assigning an appropriate designation (VHA CSC, VHA PSC, VA LHSF, or VHA SSF) for stroke care to each facility.
- (2) Ensuring that all VA medical facilities with an ED or UCC within the VISN have plans that define and establish the provision of care to patients with AIS and are consistent with national stroke policies.
- (3) Developing and submitting the VISN AIS care plan to the Chief Officer, Office of Specialty Care Services, or their designee, for review and concurrence.
- (4) Ensuring that all medical facilities providing AIS care in the VISN are submitting monthly quality indicator data as defined in paragraph 6.h.
- f. **VA Medical Facility Director.** The VA medical facility Director or designee is responsible for ensuring that:
- (1) A local plan (as detailed in paragraph 6) for the management of AIS is complete and current, and reported to the VISN Director upon any substantive change. VA medical facilities that are a VHA CSC or VHA PSC must have a stroke unit or other designated location (such as an ICU) within the medical facility, where stroke patients are admitted. Medical personnel with additional training and expertise in stroke care staff the unit.
- (2) VA medical facilities that are a VHA LHSF must have detailed and current transfer agreements for in-hospital stroke and protocols for Emergency Medical Services diversion in place to triage or transfer acute stroke patients to facilities offering an appropriate level of stroke care outside of the specified hours. In general, transfer will be to a VHA CSC, VHA PSC, or a non-VA Joint Commission or other designated CSC or PSC.
- (3) VA medical facilities that are a VHA SSF must have detailed and current transfer agreements for in-hospital stroke and protocols for Emergency Medical Services diversion in place to triage or transfer acute stroke patients to facilities offering a higher

level of stroke care. In general, transfer will be to a VHA CSC, PSC, LHSF (during operational hours), or a non-VA Joint Commission or other designated CSC or PSC. VHA SSFs can provide post-stroke medical care (excluding thrombolytic therapy), or inpatient or outpatient rehabilitation and follow-up care.

6. REQUIREMENTS FOR THE MEDICAL FACILITY AIS MANAGEMENT PLAN

The medical facility plan must include the following:

- a. Clinical plans for the rapid identification, evaluation, and treatment of patients presenting with symptoms and signs consistent with AIS. These protocols are preferably computer-based products, but may be paper-based. The protocol must include plans for managing alteplase eligible and endovascular eligible patients. **NOTE:** It is recommended that VA medical facilities follow the extended alteplase administration 4.5 hour time frame.
- b. VA medical facilities with the capacity to provide endovascular stroke treatment must include this therapy in their stroke plans. At all other VA medical facilities, plans must be developed or modified to identify and transfer patients potentially benefitting from endovascular treatment to a CSC designated by the Joint Commission or other entity able to provide intra-arterial treatment at all times.
- c. Identification of a formal stroke team at those sites designated as VHA CSC, PSC, or LHSF. The team must be available during operational hours and be able to respond in person or via tele-medicine within 30 minutes of a call.
- d. In-house radiology technicians who are able to perform non-contrast computed tomography (CT) scans at all VHA CSCs, PSCs, and at all LHSFs during designated hours of operation. Radiologists privileged to interpret non-contrast CT scans must also be available to provide interpretation of the CT scan within 15 minutes of image completion, either in-person or via tele-radiology services. In lieu of attending radiology review, experienced neurologists, or neurosurgeons who are available, may interpret imaging studies for the purpose of informing acute treatment decisions.
- e. Readily available alteplase stored in the ED and Intensive Care Unit (ICU) at every VHA CSC, PSC and LHSF. The plan must delineate inclusion and exclusion criteria that must be followed for the administration of alteplase.
- f. The patient or a legally authorized surrogate must be informed of the risks and benefits of thrombolytic therapy for AIS. Signature consent for treatment must be documented in the medical record consistent with processes described in VA policy on informed consent (i.e., VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, and VHA Handbook 1004.05, iMedConsent). If the patient/surrogate declines the administration of thrombolytics (e.g., alteplase), the progress note must document the patient's/surrogate's reason(s), if known, and the expected outcome. **NOTE:** Handbook 1004.01 outlines circumstances under which signature consent is required; processes to be followed in clinical emergencies; and processes to be followed when a patient lacks decisional capacity and there is no

available surrogate. Handbook 1004.05 outlines how the iMedConsent system can be used to facilitate access to certain educational materials and/or decision-tools about thrombolytics in AIS; processes that can streamline workflow by involving multiple clinical team members in the consent process and/or facilitate obtaining asynchronous consent or consent via telehealth; and procedures to follow when the iMedConsent system is unavailable.

- g. Plans for emergent transfer at all times to the nearest VA or non-VA CSC or PSC capable of providing AIS care must be in place at all VHA LHSFs and SSFs.
- h. Methods to capture the quality indicators used to monitor progress and improvements in AIS care, which include:
 - (1) Percentage of eligible patients given thrombolytic therapy (alteplase).
 - (2) Percentage of eligible patients receiving or transferred for endovascular therapy
- (3) Percentage of patients with symptoms of AIS that have the National Institutes of Health Stroke Scale (NIHSS) completed (https://stroke.nih.gov/resources/scale.htm).
- (a) Prior to alteplase, endovascular therapy, or transfer for patients eligible for acute treatment, or
- (b) Within 12 hours of admission for patients presenting outside of the window for acute therapies.
 - (4) Percentage of patients being screened for dysphagia before oral intake.
- i. Facility plans for the management of AIS must be available in the ED, the UCC, and at the nursing stations on the inpatient units in all VA medical facilities
- j. VA PSCs and LHSFs may use tele-medicine services as well as in-person staff to deliver required care, including tele-stroke consultation for acute stroke care, tele-radiology for image interpretation, and tele-Intensive Care Unit (ICU) services for post-alteplase inpatient care.
- k. All VA medical facilities must ensure training of front-line staff in patient care areas to allow for prompt recognition and treatment of acute stroke.

7. REFERENCES

- a. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.
 - b. VHA Handbook 1004.05. iMEDConsent™.
- c. VHA Handbook 1004.02 Advance Care Planning and Management of Advance Directives.

- d. Evaluation of Acute Ischemic Stroke Care in Veterans Health Administration Facilities. https://www.va.gov/oig/pubs/VAOIG-15-03803-26.pdf
- e. Alberts MJ, Latchaw RE, Selman WR., Shephard T, Hadley MN, Brass LM, et al. (2005). Recommendations for comprehensive stroke centers: a consensus statement from the Brain Attack Coalition. Stroke. 2005; 36(7):1597-1616.
- f. Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; on behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2018;49:e46–e99. doi: 10.1161/STR.0000000000000158.
- g. Prescribing information for Activase® (alteplase), Genentech, Revised: 01/2017. https://www.gene.com/download/pdf/activase prescribing.pdf (NOTE: This linked document is outside VA control and may not be compliant with Section 508 of the Rehabilitation Act of 1973) and https://www.activase.com/
- h. Clinical Policy: Use of Intravenous Tissue Plasminogen Activator for the Management of Acute Ischemic Stroke in the Emergency Department. American College of Emergency Physicians Clinical Policies Subcommittee (Writing Committee) on Use of Intravenous tPA for Ischemic Stroke. Ann Emerg Med. 2015 Sep;66(3):322-333.e31.https://www.ncbi.nlm.nih.gov/pubmed/26304253
- i. Pharmaceutical Use Outside of Approved Indications Guidance on "Off-label" Prescribing. Department of Veterans Affairs Center for Medication Safety, Veterans Health Administration Pharmacy Benefits Management Services VA Medical Advisory Panel and VISN Pharmacist Executives. August 2013.