CNICS Venothromboembolic (VTE) Review packet assembly

Information gathered for adjudication is based on the date generated for the potential VTE event. Common examples of VTE events include deep venous thromboses (DVT) and pulmonary embolic events (PE). Less common examples of VTE events include Budd-Chiari syndrome (hepatic vein occlusion in the liver). The CNICS chart reviewer at each site will assemble review packets that contain the following information in the following order if available:

- 1. Physician's notes closest to potential VTE date: admit notes, transfer notes, discharge notes, ER notes, in-patient consultation notes, clinic visit notes and/or autopsy reports. Both Pulmonary and cardiology consultation notes are of particular value if available as are inpatient pharmacy anti-coagulation notes. If there are discharge summaries or related information from outside hospitalizations, please include this information as well.
- 2. First 3 outpatient consultation or visits following potential VTE date.
- 3. Any inpatient admit or discharge notes in the 3 months prior to potential VTE event.
- 4. Clinic notes in the 3 months prior to the potential VTE event. This should include outpatient pharmacy anti-coagulation clinic notes. Ancillary services notes such as nutrition and podiatry, and repetitive notes such as daily wound care are not needed.
- 5. Baseline ECG (prior to current admit) if available
- 6. Baseline ECHO (prior to current admit) if available
- 7. The first two electrocardiograms (ECGs) after admission (includes ECGs obtained in the emergency department), the last ECG before discharge and the last ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event. All ECGs should include a clearly written date. Ideally, all ECGs should be placed in order of date with earliest ECG first. If a report is available for the ECG, that should be submitted as well. If one is not available, the ECG should still be submitted.
- 8. Related procedure and diagnostic test results around or following the potential VTE event. These include venograms; venous ultrasounds including duplex ultrasound, venous duplex, compression ultrasound, venous doppler, augmentation pulsed doppler, and spontaneous color doppler; impedance plethysmography; lung scan; V/Q scan; ventilation/perfusion radionuclide scan; pulmonary angiogram; chest or abdomen CT scan (this includes all chest/abdominal scans including CT angiogram, helical CT, spiral CT); MRI scans of chest, abdomen, pelvis, lower or upper extremities.
- 9. Echocardiograms during or following the potential VTE event.
- 10. D-dimer laboratory results near potential VTE event.
- 11. Related medication/prescription information specifically for anticoagulants:

Warfarin/Coumadin

Low molecular weight heparins: enoxaparin [brand lovenox], dalteparin [brand Fragmin], nadroparin, tinzaparin [brand Innohep]

Direct factor Xa inhibitors: rivaroxaban (Xarelto), apixaban (Eliquis), and edoxaban (Lixiana, Savaysa) Direct thrombin inhibitors: dabigatran

Before sending packets, the site coordinator will replace personal identifiers with the CNICS identifier. If possible, sites will also remove all HIV medications from records. This can be done by copying and pasting electronic medical record notes into a format that facilitates modification including removal of patient identifiers and HIV medications. If this is not possible, identifying information on printed materials needs to be blackened and copies made from the originals.

Completed packets will be uploaded to the CNICS VTE database.

For each event, if sites are unable to generate packets, they will be asked document why. Possible reasons include the event occurred at an outside hospital. Sites will be asked to make at least 2 attempts to request records before declaring that the information for that event is not available. Sites can also document that the

ascertainment diagnosis was an error, and therefore there is no information regarding that diagnosis to assemble. Finally, some ascertainment diagnoses are referring to events that occurred previously. In this instance, sites will be asked to try and identify the approximate timing of the earlier event. If the event occurred before a patient was enrolled in the CNICS site, the process is finished. If it occurred while in CNICS, please generate a new packet request for the earlier time period and notify Heidi of the correct date.

Any questions from sites about assembling review packets should be directed to Heidi Crane

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