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NCCN Guidelines Panel: Cancer-Associated Venous Thromboembolic Disease

On behalf of The Society of Interventional Oncology, we respectfully request the NCCN Cancer-Associated Venous Thromboembolic Disease Guideline panel review the enclosed data for inclusion in the management of cancer-associated venous thromboembolic disease.

<u>Specific Change 1: VTE-B:</u> With respect to "Contraindications to Mechanical Prophylaxis" recommend modifying "Acute DVT" to "Acute DVT (if anticoagulation is contraindicated)." Consider adding statement from FDA Clearance and reference as a footnote.

<u>FDA Clearance</u>: Compression therapy can improve pain and swelling from acute DVT, and can be safely applied following acute DVT provided that the patient can be therapeutically anticoagulated.

The following article is submitted in support of this proposed change: Rabe E, et al. Phlebology, 2018. 33(3):163-84.

<u>Specific Change 2</u>: DVT2 and DVT3: modify "consider catheter-directed pharmacomechanical thrombolysis in appropriate candidates" to "consider catheter-directed therapy (pharmacomechanical thrombolysis or mechanical thrombectomy) in appropriate candidates"

<u>FDA Clearance</u>: Pharmacologic/pharmacomechanical thrombolysis as well as an increasing number of percutaneous mechanical thrombectomy devices are either FDA approved or have 510k clearance for the treatment of acute DVT. For patients who are not candidates to receive alteplase, mechanical thrombectomy may provide an alternative therapy depending on device availability and operator experience.

The following articles are submitted in support of this proposed change: Benarroch-Gampel J et al., J Vasc Surg Venous Lymphat Disord, 2020. 8(2):174-181 Lopez R et al., J Vasc Surg Venous Lymphat Disord, 2019. 7(2): 162-168

Specific Change 3: DVT2 and DVT3, footnote "f": Please modify footnote to read: "Appropriate candidates may include: patients at risk of limb loss (e.g. phlegmasia cerulea dolens), patients who demonstrate central thrombus propagation in spite of anticoagulation, and those with moderate to severely symptomatic proximal DVT. Candidates with high bleeding risk or contraindication to fibrinolytic may be candidates for percutaneous mechanical thrombectomy."

FDA Clearance: While there is limited prospective data for catheter directed therapy in the cancer

population, data from a large multicenter RCT comparing pharmacomechanical thrombolysis to anticoagulation alone in a non-cancer population with acute proximal lower extremity DVT demonstrated reduced symptom severity and improved QOL in patients with iliofemoral DVT treated with catheter directed therapy.

The following articles are submitted in support of this proposed change:

Comerota AJ, et al. Circulation, 2019. 139(9):1162-1173.

Vedantham S, et al. New Engl J Med, 2017. 377(23):2240-2252.

<u>Specific Change 4:</u> SPVT2: Modify "Consider catheter-directed pharmacomechanical thrombectomy" to "Consider catheter-directed pharmacomechanical thrombectomy +/- TIPS"

<u>FDA Clearance:</u> Creation of a TIPS shunt has been shown to be an effective and safe means of obtaining percutaneous access to the portal venous system in order to perform pharmacomechanical thrombectomy.

The following articles are submitted in support of this proposed change:

Jiang TT, et al. World J Gastroenterol, 2017.;23(41):7470-7477.

Rosenqvist K, et al. Acta Radiologica, 2016. 57(5) 572–579

Wang MQ, et al. Abdominal Imaging, 2011. 36:390–398

Specific Change 5: SPVT2: Add "Consider TIPS" as one of the management options for patients with SPVT and portal hypertension.

<u>FDA Clearance</u>: Portal vein recanalization and TIPS creation has been shown to be effective for the management of chronic PVT with portal hypertension. For patients with acute PVT and variceal bleeding, TIPS creation may be more effective in controlling bleeding, though no improvement in overall survival for variceal bleeding has been reported.

The following articles are submitted in support of this proposed change:

Thornburg B, et al. J Vasc Interv Radiol, 2017. 28(12):1714-1721.

Salem R, et al. Transplantation, 2015. 99(11):2347-55.

Valentin N, et al. Eur J Gastroenterol Hepatol, 2018. 30(10):1187-1193.

Lv Y et al. Gut, 2018. 67(12): 2156-2168

Luo X et al. Radiology, 2015: 276(1): 286-293

We would like to thank the NCCN panel members for their time and effort in reviewing this submission.

Sincerely,

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