## **CLINICAL PRACTICE GUIDELINES**

# Chronic Limb Threatening Ischemia

2025



# **Chronic Limb Threatening Ischemia: A Call for Urgent Action in Ontario**

The importance of rapidly identifying and treating heart attacks is widely recognized—both among healthcare professionals and the public. Early intervention, risk factor management, and timely therapeutic action are critical to improving outcomes for patients experiencing a cardiac event. But what happens when a patient suffers a "heart attack of the leg"? Despite sharing similar pathophysiology and risk factors with other cardiovascular events, albeit with some important differences, the sense of urgency and awareness surrounding this condition—chronic limb-threatening ischemia (CLTI)—remains significantly lower.

CLTI represents the severe end of the spectrum in patients with peripheral arterial disease (PAD), characterized by a more than two-week history of a pulse deficit with rest pain, nighttime pain, and/or tissue loss. These patients face a high risk of losing the affected limb due to the ischemic deficit caused by reduced blood flow—closely mirroring the ischemia experienced by patients with coronary artery and cerebrovascular disease. According to a recent Canadian Institute of Health Information (CIHI) report, up to 85% of leg amputations are considered preventable. In patients who experienced a diabetes-related lower-limb amputation, 86% had a documented diagnosis of peripheral arterial disease<sup>1</sup>. Despite the profound impact of CLTI on patients and the provincial healthcare system, Ontario has historically seen limited efforts toward limb-preservation initiatives— until recently.

Ontario Health has now identified limb preservation for non-traumatic causes of amputation as a clinical priority. As part of this focus, 12 Lower Limb Preservation (LLP) Programs have been established, aiming to reduce preventable limb loss across the province. While these efforts have already shown the benefits of collaboration, innovation, and multidisciplinary care, much work remains. Notably, there is a significant lack of provincial or national guidelines to assist clinicians in the identification, diagnosis, and treatment of CLTI.

This document provides the healthcare system with several critical advancements. First, it offers a comprehensive, streamlined pathway for diagnosing, evaluating, and treating CLTI, complete with target timelines that were previously unavailable in Ontario. These targets emphasize that delays in care for CLTI patients can lead to devastating consequences, including limb loss. Second, the document introduces the concept of an "index cardiovascular event." A diagnosis of CLTI signals not only a risk to the limb but also marks a turning point in the patient's overall cardiovascular health. The same atherosclerotic processes that cause CLTI indicate active arterial disease throughout the body, significantly increasing the patients risk for major cardiovascular events. Recognizing CLTI as an index event underscores the importance of aggressive risk factor management, medical therapy, cardiovascular screening, and close surveillance to mitigate future morbidity and mortality. Third, the creation of streamlined documentation requirements

to accurately categorize the subset of peripheral arterial disease being treated **(Appendix C CIHI Special Project 380-Peripheral Artery Disease**) will allow more robust data collection in Ontario to track outcomes for this important population. Finally, the new requirement for all vascular programs to create a "'next-up'" approach to timely urgent consultation provides the healthcare system with a new template to ensure access to care for these patients.

Patients with suspected CLTI may present in a variety of settings across Ontario, seeking help for a hard-to-heal ulcer from their primary care team, presenting at an emergency department with intractable nighttime pain, or have a plantar foot wound discovered incidentally by their endocrinologist. Given the wide range of possible presentations, it is vital that healthcare providers across all sectors maintain heightened awareness of this limb-threatening condition. Every day, we hear of Ontarians facing the profound physical, emotional, and social impacts of limb loss.

At the bottom of each page of this document, you will find the phrase "Time is Tissue. Tissue is Dignity," reminding us of the urgency and importance of this work. Through timely and appropriate interventions, we can help preserve not just limbs, but the quality of life and dignity through reduced inequities for all patients across Ontario.

A heart attack of the limb.

Sincerely,

**Dr. Varun Kapila** Provincial Lead Vascular, Ontario Health

## **Letter From the Working Group Chair**

Chronic Limb Threatening Ischemia (CLTI) defines the most critical spectrum of peripheral arterial disease affecting all walks of life. Often the devastating outcome of limb loss is due to the lack of recognition of the severity of the problem and the lack of coordination of care for these patients. CLTI is also noted to have the most devastating effect on the most disadvantaged in our society. Ontario Health is truly leading the charge in a manner that will have the greatest impact on patients with this under-recognized disease as well as preserving limbs and thus human dignity.

The aim of this document is to empower practitioners, who will encounter these vulnerable patients to act in an expeditious evidence-informed manner to save limbs and ultimately save lives. The Working Group's goal was to create a document that encompasses the idea of how patients with CLTI should be managed in a comprehensive healthcare system so that they can be treated promptly and avoid amputations. Serving as *the index cardiovascular event*, guidance is provided to give further evidence-informed risk reduction strategies that will improve the health and quality of life for these patients. In addition to providing a care pathway for limb preservation, the CLTI Clinical Practice Guidelines maintain an overall bird's-eye view on the patient so that once identified, the patient can receive best evidence-informed care while not being too prescriptive, recognizing that the CLTI Clinical Practice Guidelines do not apply to individual patients but apply to groups of patients.

The aim of the CLTI Clinical Practice Guidelines is to keep the target audience broad with a few examples so that they will encompass and apply to all practitioners who encounter atrisk patients, maintaining focus to have the greatest positive impact on the patient. Truly, *Time is Tissue and Tissue is Dignity.* 

Sincerely,

#### Dr. Giuseppe Papia

Chair, Chronic Limb Threatening Ischemia Working Group

### **Take-Home Messages**

- 1. Chronic Limb Threatening Ischemia (CLTI) is considered an index cardiovascular event.
- 2. CLTI is associated with high mortality and morbidity (including major cardiovascular events such as myocardial infarction and stroke, as well as non-traumatic lower limb amputation).
- 3. Prompt referral to and assessment by a vascular specialist improves patient outcomes.
- 4. The benchmark timelines of the CLTI Care Pathway (within 30 days) outline the end-to-end assessment, investigation, and treatment of CLTI and emphasize the need for prompt care to improve patient outcomes.
- 5. Patients with CLTI remain at high risk for major adverse cardiac and limb events requiring intensive cardiovascular risk-factor medical management and lifelong surveillance to reduce the burden of disease and improve outcomes.
- 6. Early identification and management of individual cardiovascular risk factors (e.g., smoking, diabetes, hypertension, hypercholesteremia, low-quality diet and low levels of physical activity) are critical to slowing the progression of Peripheral Artery Disease (PAD) that leads to CLTI.

## **About this Document**

The Chronic Limb Threatening Ischemia Care Pathway and Clinical Practice Guidelines are designed to provide a systematic approach to care. The Care Pathway and Guidelines reflect best practice and benchmark timelines to minimize morbidity and mortality for patients with Chronic Limb Threatening Ischemia (CLTI) (Figure 1). Although these timelines may seem ambitious, they underscore the urgency necessary to meet the clinical needs of these patients.

Although the operational implementation of the CLTI Care Pathway and Clinical Practice Guidelines is beyond the scope of this document, the Working Group acknowledges that a loco-regional, coordinated approach augmenting the best practice and benchmark timelines of the Care Pathway presented in the CLTI Guidelines, may evolve. As an example, regional variability may leverage collaborative solutions to support timely clinical evaluation by utilizing digital platforms and solutions (e.g., Ontario Telemedicine Network/OTN) to support patients living in rural and remote communities by providing an alternative to extensive travel to access care in Ontario. Another example of enhancing regional access to care, is leveraging the currently defined and clearly communicated care pathways for prompt access to a vascular specialist for consultation and determination of treatment. Although regional variations may occur, the CLTI Clinical Practice Guidelines (CLTI Guidelines) and accompanying care pathway are intended to support healthcare providers in delivering of timely and effective treatment for patients with CLTI to achieve the best patient outcomes.

The CLTI Care Pathway and Clinical Practice Guidelines follow the care journey of a patient from the identification of suspected CLTI by the patient's Health Care Provider (for this document, Health Care Provider includes the Primary Care Team, or equivalent, Cardiologist, Endocrinologist, General Internal Medicine, Vascular Medicine Specialist) to a Vascular Specialist (for this document, Vascular Specialist includes Vascular Interventional Radiologist and a Vascular Surgeon) with subsequent reconnection to the patient's Health Care Provider for ongoing follow-up and lifelong surveillance.

The structure of the CLTI Care Pathway and Guidelines is:

- Section 1 Identification
- Section 2 Procedure Planning and Revascularization
- Section 3 Optimal Medical Management and Follow-up

The CLTI Guidelines use current, clinical practice recommendations and Expert Working Group consensus in their development. Where clinical practice recommendations exist in the literature, recommendation statements are included in callout boxes using, **bold black font.** Where clinical practice recommendations are lacking or unavailable, consensus among the Expert Working Group has been garnered, consensus statements are included in callout boxes with an **asterisk (\*) in bold black font.** 

# Recommendation and Consensus Statements

### Recommendations

- **Recommendation 1**: In patients with suspected CLTI and a hard-to-heal wound, prompt referral to a multidisciplinary limb preservation program, if available, or an advanced wound care team should be completed for wound evaluation and the initiation of comprehensive care and treatment <sup>8,16,17</sup>.
- Recommendation 2: <u>All wounds</u> should be managed through collaboration of an integrated, multidisciplinary wound care service with a focus on limb preservation that include vascular specialist such as vascular surgery and/or vascular interventional radiology, orthopedic or plastic surgery, chiropody/podiatry, and credentialled wound care specialists (e.g. Nursing Specialist in Wound, Ostomy and Continence/NSWOC) with support from other specialties (e.g. cardiology, endocrinology, general internal medicine, hematology, infectious disease, physiatry and vascular medicine), when available. This multidisciplinary model is a well-established example of a foot care team structure for assessing and treating arterial insufficiency to prevent limb loss<sup>13,16</sup>.
- **Recommendation 3:** All patients who smoke or who have a history of smoking should be encouraged to quit, offered support for cessation and for those who have quit, provided encouragement to remain smoke free at every encounter with a healthcare provider<sup>9,16,28</sup>.
- Recommendation 4: All patients with CLTI, in consultation with their health care provider, should consider a diet emphasizing vegetables, fruits, legumes, nuts, whole grains, and fish while limiting red or processed meats and avoiding of sugary drinks to reduce the risk of PAD progression and Major Adverse cardiac Events (MACE)<sup>16,29</sup>.
- Recommendation 5: Optimal glycemic control is critical for vascular health and all patients with diabetes or prediabetes should have diabetes education and/or follow-up with a specialist to optimize glycemic targets<sup>34</sup> with a priority on medications shown to decrease MACE<sup>9,16</sup>.
- **Recommendation 6**: As part of the perioperative planning process, each patient's individual anatomical and physiological circumstances should be considered when determining the approach for additional diagnostic imaging<sup>8,16</sup>.
- Recommendation 7: In patients for whom revascularization is not a suitable option, the goals for care remain the same: improving wound healing and symptom management, relieving pain and suffering, reducing mortality, and preventing chronic deconditioning, disability, and major amputation<sup>8,16</sup>.

- **Recommendation 8:** Following revascularization, the gold standard for antithrombotic therapy includes low dose anticoagulant (rivaroxaban) and acetylsalicylic acid (ASA) should be considered where no contraindications or exceptions exist (e.g., bleeding risk or existing anticoagulation therapy) in addition to cholesterol lowering medications (e.g. statins) to reduce MACE and Major Adverse Limb Events (MALE) <sup>2,9,15,41</sup>.
- Recommendation 9: Baseline surveillance and evaluation of restenosis, utilizing Doppler ultrasound (DUS) with hemodynamic testing such as the Ankle Brachial Index (ABI) or Toe Brachial Index (TBI) should occur early in the post revascularization period <sup>44</sup>.
- Recommendation 10: Ongoing follow-up should be part of a lifelong surveillance program and should include an annual clinical assessment and monitoring of patient compliance with key medical and lifestyle treatments for the reduction of MACE and MALE<sup>44</sup>.

### **Consensus Statements**

- Consensus Statement 1: To support the early identification of CLTI and prevent limb morbidity or limb loss, health care providers involved in managing patients with all forms of PAD and/or previous cardiac and/or cerebrovascular disease should familiarize themselves with the 2022 Canadian Cardiovascular Society (CCS) Guidelines for PAD. Additional Canadian Cardiology Society resources and international practice guidelines are available for review in Appendix A.
- **Consensus Statement 2:** When possible, a first-line, non-invasive assessment of CLTI should include DUS combined with ABI (or TBI and Pulsed Wave Recordings [PVR], if available). The **urgent** DUS referral, arterial examination, and vascular imaging report should be completed and provided to the referring physician within 72 hours for patients with suspected CLTI.
- **Consensus Statement 3:** All patients with clinical findings and a Lower Extremity Arterial Duplex Ultrasound (DUS) suggestive of CLTI should be referred for urgent assessment (within one week) by a vascular specialist.
- **Consensus Statement 4**: All patients should receive evidence-based, non-operative medical therapies along with strategies for lifestyle behavior modification. They should have access to comprehensive, continuous primary healthcare to optimize chronic disease management and lifestyle interventions, ultimately reducing MACE and MALE.
- Consensus Statement 5: As part of the perioperative planning process, within two weeks of the vascular specialist consultation, all patients should receive additional imaging (e.g., Computed Tomography Angiography [CTA] or Magnetic Resonance Angiography [MRA]) as determined by the vascular specialist. At their discretion, direct referral for conventional angiography may be reasonable when DUS or other preoperative tests indicate purely tibial disease.

- **Consensus Statement 6:** Following revascularization, vascular specialist follow-up should be completed within 30 days of discharge to assess recovery, wound healing, infection, ischemic pain, revascularization failure, or worsening symptoms, and to ensure compliance with medications and therapeutic lifestyle interventions.
- **Consensus Statement 7:** Ongoing encounters with the patient's healthcare provider (e.g., Primary Care Team or Vascular Medicine Specialist, if available) should be encouraged before and after intervention as part of a strong surveillance program for comprehensive cardiovascular risk management.
- **Consensus Statement 8:** All vascular programs should have standardized, intensive, and structured follow-up protocols available to every patient post-revascularization.

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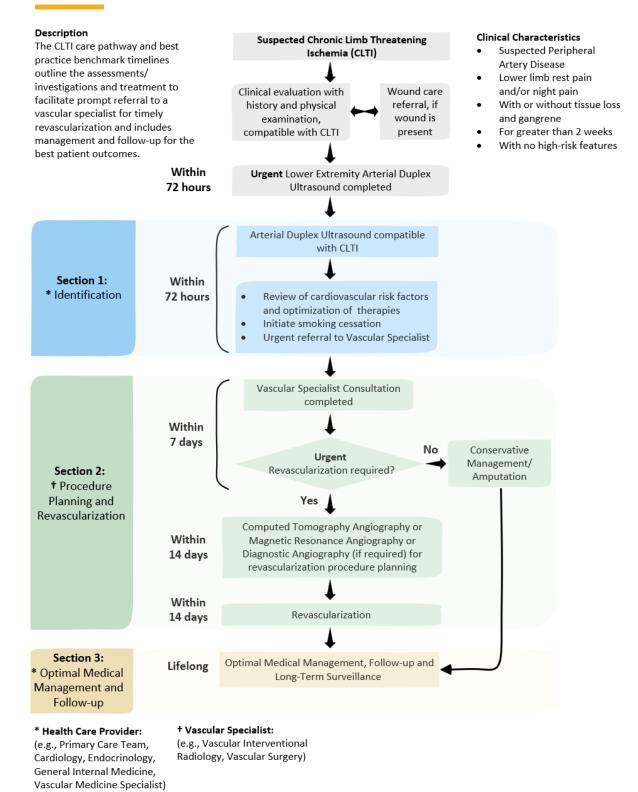
### Disclaimer

The following Chronic Limb Threatening Ischemia Care Pathway (Figure 1) is evidenceinformed and contains the consensus opinions of an Ontario Health working group, comprised of health care professionals. The information contained in this care pathway forms part of the Chronic Limb Threatening Ischemia Clinical Practice Guidelines in Ontario (the CLTI Guidelines), but it is not intended to constitute a standard of care, nor is it intended to substitute the professional judgment of health care professionals.

The treatment and management of Chronic Limb Threatening Ischemia may vary due to a variety of factors. As such, healthcare professionals may encounter circumstances where this care pathway requires adjustments, is not appropriate, or does not apply. For example, a healthcare professional may determine that the timelines contained in this care pathway need to be shortened or lengthened based on clinical judgment, patient presentation, or other circumstances.

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### Figure 1: Care Pathway for Suspected Chronic Limb Threatening Ischemia (CLTI)



### Introduction

The Chronic Limb Threatening Ischemia (CLTI) Clinical Practice Guidelines (CLTI Guidelines) aim to minimize the variation in care that contributes to delays in treatment, which can result in increased morbidity (including amputations) and mortality for patients with CLTI. The severity of CLTI and the poor outcomes associated with the most advanced form of Peripheral Arterial Disease (PAD) have been overlooked for many years. The CLTI Guidelines and Care Pathway recognize the urgency and importance of prompt access to care through enhanced awareness of a group of patients who have fallen under the radar for too long.

The CLTI Care Pathway applies best practice benchmark timelines to reinforce the need for prompt identification and access to treatment with the urgent referral to a vascular specialist. The CLTI Guidelines provide a framework and expectation for the management of CLTI in Ontario. The addition of optimal medical management and lifelong follow-up to the Care Pathway and CLTI Guidelines aims to improve the poor outcomes, including mortality and morbidity (e.g., the reduction of amputations), for this vulnerable patient population through ongoing surveillance.

A simple and specific definition of CLTI is a critical enabler for patient identification, ensuring the prompt, urgent referral to a vascular specialist for limb- and life-saving care.

The CLTI Guidelines define Chronic Limb Threatening Ischemia (CLTI) as

- Lower extremity rest pain and/or nighttime pain,
- With or without tissue loss,
- For a period of greater than 2 weeks,
- In the presence of PAD and the absence of high-risk features.

#### **Special Note Regarding Patients with Emergent Issues**

Patients with high-risk features such as tissue loss with exposed bone or tendon, infection, evidence of osteomyelitis, and/or signs of acute limb ischemia (pain, pulseless limb, pallor, poikilothermia, paresthesia, and paralysis) require emergent intervention and should be directed to the nearest emergency department or the closest hospital with a vascular program.

### The CLTI Care Pathway, best practice benchmark timelines, and CLTI Clinical Practice Guidelines do not apply.

#### **CLTI, an Index Cardiovascular Event**

PAD and its most severe manifestation, CLTI, are indications of systemic atherosclerosis, sharing a similarly poor prognosis as coronary artery disease and cerebrovascular disease. This most severe manifestation of PAD is a precursor to future cardiovascular events. CLTI, as an index cardiovascular event, signals poor overall cardiovascular health, leading to increased morbidity and mortality, and should be treated with the same aggressive approach as atherosclerotic disease in other vascular beds. Upon developing CLTI, the natural history of a patient changes. This individual is now at significantly elevated risk for the development of global vascular disease events. These events, often called major adverse cardiac events (MACE) or major adverse limb events (MALE), can be mitigated with the early initiation or intensification of management of the patient's risk factor profile<sup>2</sup>. Intense secondary prevention and ongoing optimal medical management with best practice guidance directed risk factor interventions through long-term surveillance are critical to reduce the burden of this disease<sup>3</sup> and improve overall patient survival.

#### Wound Care and Off-loading

PAD is a progressive atherosclerotic narrowing of the arteries of the lower extremities that develops from exposure to the same atherosclerotic disease risk factors (e.g., diabetes, hypertension, hyperlipidemia, smoking, poor diet, and low levels of physical activity) as ischemic heart disease and cerebrovascular disease<sup>4,5</sup>. The non-linear progression of PAD contributes to a heterogeneous patient population, resulting in a wide variety of presentations, including little to no symptoms, leg or buttock pain brought on by bouts of exercise or exertion that subsides with rest (i.e., claudication), sudden ischemic events (i.e., Acute Limb Ischemia/ALI), and the development of the most severe and debilitating, CLTI<sup>6</sup>. CLTI is associated with high mortality, poor quality of life, is a marker of severe, generalized atherosclerosis, and is a major contributing factor to lower limb amputations<sup>4,7</sup>.

CLTI has an almost 50% mortality rate within 5 years, a more dire outcome than most cancers, with approximately 20% of patients experiencing limb loss at 1 year<sup>8,9,10,11,12</sup>. Contributing to these poor outcomes is the high burden of co-morbid diabetes and the impact of the social determinants of health experienced by a subset of these patients. Key findings from the 2024 CIHI Report on Diabetes and Lower Limb Amputations highlight the influence of lower-income neighborhoods, lower high school completion rates, higher social deprivation, and rural and remote communities on lower limb amputation rates. Males living in the lowest-income neighborhoods experience 8 times higher lower leg amputation rates than their higher-income neighborhoods rate of leg amputation compared with those living in more accessible (urban) areas<sup>1</sup>. The 2024 CIHI findings support Ontario research from 2020, where geography influenced clinical outcomes, with higher amputation rates in rural and northern communities<sup>13</sup>.

Efforts to manage the poor outcomes associated with CLTI include prompt assessment and treatment with revascularization by a vascular specialist, and the initiation of secondary prevention aimed at cardiovascular risk factor management and antithrombotic therapy<sup>14,15</sup>.

Early engagement of the integrated, multidisciplinary care team, when available, to address the clinical needs of patients with CLTI, patient complexity, and the multiple medical conditions occasionally associated with the condition, through collaborative partnerships and clinical expertise of practitioners and medical experts focused on limb preservation, is well documented throughout the literature as a strong component of care for patients with CLTI<sup>8,16</sup>.

\*Consensus Statement 1: To support the early identification of CLTI and prevent limb morbidity or limb loss, health care providers involved in managing patients with all forms of PAD and/or previous cardiac and/or cerebrovascular disease should familiarize themselves with the 2022 <u>Canadian Cardiovascular Society (CCS) Guidelines for PAD</u>. Additional Canadian Cardiology Society resources and international practice guidelines are available for review in **Appendix A**.

### **Section 1: Identification**

Individuals living with co-morbid conditions (e.g., diabetes [DM], chronic kidney disease [CKD], and other forms of cardiovascular disease such as heart disease and stroke) are at significantly higher risk. Health care provider awareness of patients at risk for developing CLTI is critical for promoting prompt identification. The clinical findings of lower limb rest pain, nighttime pain, and/or a hard-to-heal wound or gangrene on the lower limb, in the absence of lower extremity pulses, can be discovered by a healthcare provider (e.g., cardiologist, endocrinologist, general internal medicine (GIM) provider, primary care team, or vascular medicine specialist) as part of routine follow-up, clinical screening, a clinical examination, and/or part of a long-term management and surveillance program. A healthcare provider, working within their scope of practice, can identify the signs and symptoms to support the prompt diagnosis of suspected CLTI and initiate both preliminary care and urgent referral to a vascular specialist (see Figure 1, Section 1-Identification).

#### **Clinical Evaluation**

Confirmation of CLTI requires the differentiation of its signs and symptoms from other medical issues (e.g., neurogenic, musculoskeletal). A comprehensive clinical evaluation, which includes a complete physical examination, patient history, and, when possible, urgent diagnostic imaging (e.g., lower extremity arterial duplex ultrasound/DUS) with non-invasive testing, is an initial step in differentiating CLTI from other conditions.

In the presence of a hard-to-heal wound, wound staging using a validated tool (e.g., Rutherford, WIfl) can be useful to inform wound severity, wound recovery, and wound healing. Prompt referral for advanced wound management by skilled clinicians, with the goal of minimizing tissue loss, improving wound healing, and managing infection, is a critical step and an important early intervention.

**Recommendation 1**: In patients with suspected CLTI and a hard-to-heal wound, prompt referral to a multidisciplinary limb preservation program, if available, or an advanced wound care team should be completed for wound evaluation and the initiation of comprehensive care and treatment<sup>8,16,17</sup>.

#### Wound Care and Off-loading

Not all patients with CLTI experience tissue loss, but for those individuals with a hard-to-heal wound and/or gangrene of the lower limb, prompt assessment and treatment by a wound care specialist, infection management, and urgent referral to a vascular specialist are required<sup>8</sup>. As a first-line intervention for the care and treatment of hard-to-heal wounds, wound cleansing, debridement, and dressing by a wound care specialist, when available (e.g., chiropodist/podiatrist, nurse specialized in wound, ostomy, and continence (NSWOC)) with educational support and counselling is essential. Referral to a multidisciplinary lower limb preservation team, when available, and the possibility of advanced therapies should be considered to support the healing process<sup>17</sup>. More information on the Ontario Framework for Lower Limb Preservation can be accessed through the <u>Ontario Framework for Lower Limb Preservation</u>.

Off-loading is an essential component of wound care, and its importance in promoting healing of a hard-to-heal wound cannot be overstated. Where appropriate, the prescription of off-loading and/or mobility devices to support healing should be considered. The process of healing a hard-to-heal wound is far from linear and takes time, patience, and expertise. Even with good wound management (including revascularization, off-loading, and regular follow-up by a certified wound care specialist), wound healing can be slow, taking many weeks and months. Wound closure within a period of 12 weeks is considered a reasonable goal in the setting of advanced wounds<sup>18</sup>.

**Recommendation 2**: <u>All wounds</u> should be managed through collaboration of an integrated, multidisciplinary wound care service with a focus on limb preservation that include vascular specialist such as vascular surgery and/or vascular interventional radiology, orthopedic or plastic surgery, chiropody/podiatry, and credentialled wound care specialists (e.g. Nursing Specialist in Wound, Ostomy and Continence/NSWOC) with support from other specialties (e.g. cardiology, endocrinology, general internal medicine, hematology, infectious disease, physiatry and vascular medicine), when available. This multidisciplinary model is a well-established example of a foot care team structure for assessing and treating arterial insufficiency to prevent limb loss<sup>13,16</sup>.

#### A Note Regarding Hyperbaric Oxygen Therapy (HBOT) in patients with CLTI

There may be a role for the use of HBOT to accelerate healing in patients with diabetes and nonhealing neuropathic ulcers and low-grade ischemia who have failed to respond to traditional wound care. However, HBOT does not prevent major limb amputation and should not be used as an alternative to revascularization in patients with CLTI<sup>8</sup> (page S63).

#### The Multidisciplinary Team

All CLTI patients can benefit from an interprofessional, multidisciplinary team approach (e.g., limb preservation clinic, hot foot clinic, foot care clinic, emergency assessment clinic) to minimize tissue loss in hard-to-heal wounds. Among CLTI patients, the interprofessional, multidisciplinary team approach has been shown to improve referral efficiency and access to limb preservation care, reducing the number of major amputations<sup>19,20</sup>. Clinics structured with the close collaboration of vascular specialists (e.g., vascular interventional radiologists, vascular medicine specialists, vascular surgeons) offer one approach with proven results and should be considered to reduce delays in care during treatment<sup>8,13,16</sup>.

Although the composition of the interprofessional, multidisciplinary teams may vary by region, ensuring access to expertise and resources with the knowledge, skills, and abilities to support limb preservation for patients with CLTI is critical. In circumstances where these resources are not readily available within a multidisciplinary team, developing care pathways to access the expertise and resources is recommended. This approach ensures all patients receive the best possible care, regardless of geography.

#### Lower Extremity Arterial Duplex Ultrasound

Lower Extremity Arterial Duplex Ultrasound (DUS) or arterial doppler includes grayscale and doppler imaging of the peripheral vessels and is widely considered an excellent first-line assessment of the vasculature in patients with suspected CLTI. DUS is available in many geographical areas across Ontario. Where timely access to DUS may result in delays to identification and treatment, healthcare providers and regional partners are encouraged to develop a loco-regional approach to meet the best practice benchmark timelines.

DUS provides an accurate and reliable assessment of CLTI with no risk of radiation or contrast-induced nephropathy. DUS can be performed in combination with hemodynamic testing, including Ankle Brachial Index (ABI), Toe Brachial Index (TBI), and Pulsed Volume Recordings (PVR), reducing appointment burden on patients. DUS is an excellent modality for assessing the patency of the tibial arteries as it is less impacted by calcification than other modalities, such as Computed Tomography Angiography (CTA).

**\*Consensus Statement 2:** When possible, a first-line, non-invasive assessment of CLTI should include DUS combined with ABI (or TBI and Pulsed Wave Recordings [PVR], if available). The **urgent** DUS referral, arterial examination, and vascular imaging report should be completed and provided to the referring physician within 72 hours for patients with suspected CLTI.

DUS is also recommended as part of the long-term surveillance program (see Section 3 – Optimal Medical Management and Follow-up) following revascularization<sup>8</sup>.

#### **Hemodynamic Testing**

As part of a DUS, patients with CLTI or suspected CLTI will simultaneously complete hemodynamic testing such as the ABI. The ABI should be interpreted and described based on best practice. In patients with suspected CLTI and concomitant DM and CKD, the ABI may be abnormally elevated due to the calcification of the posterior tibial artery. For these patients, completion of a TBI should be arranged to better ascertain the extent and severity of ischemia<sup>8</sup>.

#### **Referral to Vascular Specialist and Cardiovascular Risk Factor Management**

DUS findings compatible with CLTI trigger an urgent referral to a vascular specialist. This referral will lead to a vascular consultation, the assessment of cardiovascular risk factors, and the initiation and/or titration of key medical cardiovascular risk factor therapies (e.g., statins, blood pressure medications, blood thinners, and lifestyle behavior modification strategies, such as smoking cessation)<sup>16</sup>.

**\*Consensus Statement 3**: All patients with clinical findings and a Lower Extremity Arterial Duplex Ultrasound (DUS) suggestive of CLTI should be referred for urgent assessment (within one week) by a vascular specialist.

Patients with CLTI often present with multiple comorbidities, such as DM, hypertension, and coronary artery disease, making management complex. Optimizing medical management before surgical or endovascular intervention is essential to improving outcomes. Optimal medical management stabilizes systemic conditions, reduces procedural risks, and promotes post-intervention recovery. Comprehensive medical optimization, including antiplatelet therapy, glycemic control, lipid management, and smoking cessation, ensures patients are in the best possible condition to undergo revascularization, enhancing both limb preservation rates and long-term survival<sup>21,22</sup>.

Current research findings show that less than 50% of patients receive optimal, non-operative, evidence-based medical therapies, with even fewer patients supported with strategies for lifestyle behavior modification (e.g., smoking cessation, dietary and exercise advice)<sup>11,15,23,24,25</sup>. Evidence from the BEST-CLI trial found that despite a high proportion of comorbidities within the CLTI cohort (87% diagnosed with hypertension, 69% with DM, 73% with hyperlipidemia, and 35% current smokers), only 25% of patients met all four criteria for optimal medical therapy for cardiovascular risk factor management for best patient outcomes (controlled blood pressure, not currently smoking, use of one lipid-lowering medication, and the use of an antiplatelet agent)<sup>26</sup>.

**\*Consensus Statement 4**: All patients should receive evidence-based, non-operative medical therapies along with strategies for lifestyle behavior modification. They should have access to comprehensive, continuous primary healthcare to optimize chronic disease management and lifestyle interventions, ultimately reducing MACE and MALE.

#### **Requirement for Designated Vascular Programs in Ontario**

Each designated vascular program in Ontario must implement a programmatic approach for the prioritized shared scheduling of CLTI referrals to facilitate rapid vascular consultation (within 1 week of referral). This priority shared access will ensure CLTI patients with life- and limb-threatening conditions, who do not require immediate hospital admission, receive urgent contact for vascular care.

While each program may implement a different approach, the process can include but is not limited to,

- Scheduling patient consultations for the next available clinic appointment, regardless of the physician indicated on the referral.
- Maintaining rapid access appointment slots specifically for urgent cases.
- Modifying referral forms to include "Urgent Referral" and/or "Next available/On-Call Surgeon" (see Appendix D for an example of a referral form supporting this requirement).

This programmatic approach will ensure access to urgent and equitable vascular care among Ontarians, regardless of geography. A designated vascular program that does not satisfy the program requirements, including this new additional requirement, will be expected to collaborate, as needed, with Ontario Health, their Ontario Health Region, and the Ministry of Health to develop and implement an Improvement Action Plan to meet the Program Standards. A full outline of expectations can be found in the <u>Ontario Designated Vascular Program Standards</u>.

#### **Smoking Cessation**

The importance of smoking cessation is well-established, as it reduces perioperative risk and improves healing and post-surgical outcomes<sup>27</sup>. All patients are encouraged to remain smoke-free or take steps to reduce smoking, with the goal of complete smoking cessation. Referral to smoking cessation programs and/or specific interventions with follow-up is strongly recommended. Patients should not be encouraged to use vaping products as part of a smoking cessation strategy<sup>28</sup>.

See Appendix E for patient resources to support smoking cessation, nicotine replacement and treatment programs (e.g., Smoker's Helpline, Centre for Addiction and Mental Health - CAMH **S**moking **T**reatment for **O**ntario **P**atients/**STOP** Program, Pharmacy services in the local neighbourhood) through Health811.

**Recommendation 3**: All patients who smoke or who have a history of smoking should be encouraged to quit, offered support for cessation and for those who have quit, provided encouragement to remain smoke free at every encounter with a healthcare provider<sup>9,16,28</sup>.

#### **Healthy Eating**

Unbalanced diets, low-quality foods, and sub-optimal eating behaviors promote illness and disease progression. Poor eating behaviors are relevant predictors of poor cardiovascular disease (CVD) outcomes<sup>29</sup>. Determining appropriate dietary guidance to meet the medical complexities and treatments of patients with CLTI requires the knowledge, skills, and resources of a skilled healthcare provider<sup>29</sup>. This should include a comprehensive dietary evaluation and medical history by a Primary Care Team or Registered Dietitian<sup>30</sup>.

See Appendix E for patient resources for healthy eating and referral options for a Registered Dietitian through Health811.

Improving dietary patterns and choices, with a whole food, plant-rich food pattern (more vegetables, less animal, dairy, egg, meat, and processed food consumption), has been shown to reduce MACE, especially in high-risk PAD patients<sup>16</sup>.

**Recommendation 4:** All patients with CLTI, in consultation with their health care provider, should consider a diet emphasizing vegetables, fruits, legumes, nuts, whole grains, and fish while limiting red or processed meats and avoiding of sugary drinks to reduce the risk of PAD progression and Major Adverse cardiac Events (MACE)<sup>16,29</sup>.

#### **Optimal Glycemic Management**

Hyperglycemia directly impacts vascular risk. Post-revascularization hyperglycemia is associated with increased rates of limb loss. Optimizing prediabetes and diabetes management can significantly improve both microvascular and macrovascular complications<sup>31,32</sup>. All patients should be connected with a Diabetes Education Centre (DEC) or similar, with encouragement and support to achieve optimal glycemic targets. Referral to specific diabetes education centers and/or Endocrinologists for complex patients requiring insulin may improve hyperglycemia management. It is strongly recommended that patients with diabetes or at risk of developing DM, with known vascular disease, have ongoing follow-up at regularly scheduled intervals that are appropriate for their medical history<sup>33</sup>.

See Appendix E for patient resources for living and thriving with diabetes, access to Diabetes Education Centres (DECs) in your area through Health811.

**Recommendation 5:** Optimal glycemic control is critical for vascular health and all patients with diabetes or prediabetes should have diabetes education and/or follow-up with a specialist to optimize glycemic targets<sup>34</sup> with a priority on medications shown to decrease MACE<sup>9,16</sup>.

# Section 2: Procedure Planning and Revascularization

After the vascular consultation, urgent revascularization planning and scheduling may be required. Additional imaging (e.g., computed tomography/CTA, magnetic resonance/MRA, conventional, and carbon dioxide angiography) is critical for perioperative planning to assess patient risk, limb severity, and the anatomic pattern of disease (PLAn). This imaging guides the appropriate revascularization approach (open, endovascular, or hybrid) based on the patient's anatomical and physiological situation<sup>8,16</sup>.

**Recommendation 6**: As part of the perioperative planning process, each patient's individual anatomical and physiological circumstances should be considered when determining the approach for additional diagnostic imaging<sup>8,16</sup>.

#### **Computed Tomography Angiography (CTA)**

CTA provides a timely, accurate assessment of the lower extremity vasculature, generating highresolution, contrast-enhanced images. After confirming a CLTI diagnosis, CTA should be considered for revascularization planning. In some cases, CTA may also be used for the initial screening and diagnosis of CLTI when DUS is unavailable. With CTA, there is a risk of acute kidney injury (nephropathy) in patients with impaired renal function (Glomerular Filtration Rate [GFR] < 30) that must be considered. Although there is a theoretical long-term risk of complications from radiation exposure, this is likely a small concern given the typical age group of CLTI patients and with modern CTA techniques<sup>8</sup>.

#### Magnetic Resonance Angiography (MRA)

Gadolinium-enhanced MRA offers similar images to CTA without the risks of radiation exposure or contrast-induced nephropathy. It is the best non-invasive imaging modality for assessing tibial vessels and is accurate for determining targets for distal bypass

The routine use of MRA is limited by access to MRI, prolonged scan time, and the risk of nephrogenic systemic fibrosis in patients with impaired renal function (GFR < 30). MRA is not usually the first-line imaging for CLTI screening, diagnosis, or revascularization planning. However, in settings with limited access to CTA, or in patients with renal dysfunction, and where MRA expertise is available, it may be considered for CLTI diagnosis or revascularization planning. For patients with severe renal insufficiency or acute-on-chronic kidney disease, non-contrast MRA techniques or CO2 angiography may be used for diagnosis or treatment planning.

\*Consensus Statement 5: As part of the perioperative planning process, within two weeks of the vascular specialist consultation, all patients should receive additional imaging (e.g., Computed Tomography Angiography [CTA] or Magnetic Resonance Angiography [MRA]) as determined by the vascular specialist. At their discretion, direct referral for conventional angiography may be reasonable when DUS or other preoperative tests indicate purely tibial disease.

#### Revascularization

The goal of revascularization is to improve lower extremity blood flow to the affected limb, facilitate improved wound healing and tissue regrowth, reduce ischemic symptoms, and enhance limb preservation<sup>16,37,38</sup>.

Prompt access to revascularization is the cornerstone of treatment with successful revascularization aiding in wound healing and symptom management in patients with CLTI. To minimize treatment delays, priority access to a vascular specialist (Requirement for Designated programs, page 18) will ensure patients with life and limb threatening conditions such as CLTI, not requiring immediate admission to hospital, receive *urgent* contact with vascular care.

The type of revascularization procedure performed (e.g., open, endovascular or hybrid) is determined by the vascular specialist and is informed by several factors including the anatomic pattern of disease, timeline of access to procedural/operating room time, patient's overall health status, and degree of limb threat, as part of the patient consultation<sup>16,39</sup>.

Revascularization should be attempted prior to amputation whenever safe and appropriate, as determined by a vascular specialist. Depending upon the degree of tissue loss, gangrene and/or infection, staged revascularization, or simultaneous revascularization with wound debridement and/or minor amputation may be considered to minimize the extent of tissue loss and enhance wound healing<sup>9,16</sup>.

# Requirement for all programs completing lower extremity revascularization procedures: CIHI Project 380 Peripheral Artery Disease

Completion of CIHI Project 380 Peripheral Artery Disease is mandated in Ontario by the Ministry of Health for all Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) abstracts when a specific lower extremity revascularization intervention is recorded.

The vascular specialist (e.g., Vascular Interventional Radiologist or Vascular Surgeon) performing the limb saving procedure, must document the specific stage of PAD in the patient record (e.g., Consultation Note, Operative Note, Procedural Note, and/or Discharge Summary).

The standardized documentation of the stage of PAD in the patient medical record is required and includes recording only 1 stage of PAD from the list below.

- 1. Asymptomatic peripheral artery disease
- 2. Intermittent claudication
- 3. Asymptomatic peripheral artery disease primary assisted patency
- 4. Chronic limb-threatening ischemia/Critical limb ischemia (CLTI/CLI)
- 5. Acute limb ischemia

See **Appendix C CIHI Project 380 Peripheral Artery Disease** for information regarding CIHI Project 380 and the requirements for Ontario programs completing these procedures and interventions.

#### **Patient Resources**

Following revascularization, medical and non-medical therapy optimization and compliance is essential to reduce MACE and MALE. In a 2024 CIHI report, only 54% of patients with diabetes who were hospitalized following a lower extremity amputation, and/or treatment for an ulcer, gangrene, or infection, reported receiving enough information about what to do if they worried about their condition or treatment after discharge<sup>35</sup>. Moreover, following hospitalization for an above ankle amputation, ankle, foot or toe amputation or for treatment of a diabetes related foot ulcer, patients were at high risk for readmission with 12-month readmission rates for another diabetes-associated lower limb complication at 19%, 37% and 31% respectively<sup>1,35</sup>.

In a recent 2024 study, good quality, reliable sources of patient education were identified as key enablers to boost knowledge and awareness regarding the dire complications associated with CLTI that can contribute to MACE and MALE. Patient education was shown to reduce delays in treatment and improve decision making and self management<sup>36</sup>. As part of a long term strategy for vascular health, patient education and counselling emphasizing the importance of medication compliance and behaviour modification (e.g., smoking cessation) is critical to enhance patient knowledge and awareness of complications that can occur during and after treatment<sup>36</sup> and therefore potentially positively impacting patient outcomes.

See Appendix E for patient resources available through Health811.

#### **Conservative Management**

Although prompt revascularization is the cornerstone of CLTI treatment, in some patients due to anatomy, physiology, and/or patient specific considerations and co-morbidities, revascularization may not be a suitable option. Management of ischemic symptoms, specialized wound care, optimal cardiovascular risk reduction and other CLTI related considerations should be managed in partnership by the primary health care provider/team and the multidisciplinary limb preservation clinic, where available. When feasible, routine reassessment for the appropriateness of revascularization should be completed on a routine basis, if indicated<sup>8,16</sup>.

For this specific subset of CLTI patients, ischemic pain management may be augmented by palliative and alternative therapies. It is important to note, these approaches and therapies may not be widely available or appropriate treatment options for each individual circumstance.

**Recommendation 7:** In patients for whom revascularization is not a suitable option, the goals for care remain the same: improving wound healing and symptom management, relieving pain and suffering, reducing mortality, and preventing chronic deconditioning, disability, and major amputation<sup>8,16</sup>.

#### The Role for Amputation

Despite best efforts and timely access to care, some patients with CLTI may not be suitable candidates for revascularization due to a variety of factors including anatomic, physiologic, or other considerations at any time point. These patients, based on imaging, have no optimal arterial pathway (TAP - target arterial path) to restore in-line flow to the lower extremity and/or have no visible arterial circulation (desert foot)<sup>8,40</sup>. For these patients, amputation may be necessary to reduce the level of amputation, palliate pain symptoms, manage infection, enhance wound healing and preserve independent ambulation in patients who are capable<sup>8</sup>. Although this group of patients may require an amputation, they may also benefit from revascularization to improve the inflow thereby reducing the level of amputation<sup>8</sup>.

# Section 3: Optimal Medical Management and Follow-up

#### **Optimal Medical Management**

High-risk cardiovascular patients include those with two or more vascular beds affected (known as polyvascular disease), heart failure, renal insufficiency, or diabetes. PAD patients face a >10% risk of major vascular events over 30 months, especially if they had prior lower arterial revascularization, amputation, or severe ischemic symptoms (e.g., Fontaine III/IV) <u>OR</u> if they have at least 1 high-risk comorbidity, including polyvascular disease, heart failure, renal insufficiency or DM<sup>9,41</sup>.

A population registry of vascular patients treated with rivaroxaban and aspirin found the highest cumulative incidence of major adverse cardiovascular or limb events (MACE/MALE) in those with polyvascular disease, at 13.58% over 24 months. The incidence rate was 9.16 per 100 patient-years in polyvascular patients, compared to 2.48 per 100 patient-years in those without polyvascular disease<sup>41,42</sup>. Due to their higher absolute risk, this subgroup of PAD patients benefits most from aggressive medical therapy including lipid, blood pressure and glucose lowering therapy, as well as intensified antithrombotic therapy with dual pathway inhibition with low dose aspirin and rivaroxaban.

**Recommendation 8:** Following revascularization, the gold standard for antithrombotic therapy includes low dose anticoagulant (rivaroxaban) and acetylsalicylic acid (ASA) should be considered where no contraindications or exceptions exist (e.g., bleeding risk or existing anticoagulation therapy) in addition to cholesterol lowering medications (e.g. statins) to reduce MACE and Major Adverse Limb Events (MALE)<sup>2,9,15,41</sup>.

These findings reinforce that successful outcomes in CLTI management depend not only on revascularization but also on ensuring adherence to best medical therapies including proven strategies for antithrombotic therapy, lipid management, blood pressure control and optimal glucose management, lifestyle modification, and careful management of co-morbidities<sup>9</sup>. Patients with CLTI require assessment for CV risk factors and polyvascular disease. Recognizing the heightened risk for patients with polyvascular disease is particularly crucial, as these patients require more aggressive treatment to prevent adverse cardiovascular events. The goal of this medical management strategy is not only to alleviate symptoms but also to reduce the high burden of cardiovascular morbidity and mortality in this vulnerable population.

High-risk patients, such as those post-revascularization and/or post amputation, should receive intensive secondary prevention, including antithrombotic therapy, statins, and smoking cessation counseling. Clinic assessments should screen for smoking, physical activity, diet including food pattern consumption, hypertension, DM, along with medication reconciliation. Patients should receive education about PAD including support for smoking cessation and referral to exercise programs. Communication with other care providers and performance tracking are essential for improving adherence<sup>43</sup>.

The CCS 2022 Guidelines for PAD<sup>9</sup> recommend the following key medical and lifestyle treatments for PAD patients:

- Antithrombotic Therapy: Using low dose rivaroxaban with aspirin where no contraindications or exceptions exist (e.g., bleeding risk, already on alternative anticoagulation), for high-risk patients to reduce cardiovascular and limb events.
- Blood Pressure Control<sup>‡</sup>: Angiotensin Converting Enzyme (ACE) inhibitors or Angiotensin Receptor Blockers (ARBs) are preferred, especially in patients with hypertension and other cardiovascular risks.
- **Dietary Changes‡:** Promoting a heart-healthy diet to improve cardiovascular health.
- **Glycemic Control**<sup>‡</sup>: Optimizing management of diabetes, especially agents that are proven to reduce MACE and the risk of complications like amputation.
- High-intensity statins‡ are recommended to manage dyslipidemia.
- Smoking Cessation: Essential for all PAD patients; offer pharmacotherapy (e.g., nicotine replacement, smoking cessation aids by prescription) and behavioral support (see Appendix E for specific resources and programs)
- **Supervised Exercise Programs:** Encouraging walking programs to improve symptoms and walking distance.
- Discharge planning and follow-up either via cardiac rehab or vascular medicine assessment.

**‡** Refer to current best practice and relevant clinical practice guidance documents for specific targets for these key treatments.

#### Follow-up

The increased risk for revascularization failure, restenosis and symptom deterioration continues for up to 2 years following revascularization. The identification of adverse clinical issues early in their development, with routine, scheduled follow-up, immediate post revascularization (the initial 30 days), mid-term (30 days to 12 months) and long-term (beyond 12 months), is a strategy to mitigate this risk<sup>44</sup>. In some circumstances, repeated revascularization procedures may be required until wound healing and limb preservation is achieved.

#### Initial Follow-up – the first 30 days

The initial post revascularization period monitors for signs and symptoms of restenosis or deterioration and focuses on patient recovery and the improvement of wound healing, symptom relief, tissue regrowth and enhancing quality of life while focusing on optimizing medical therapies, and monitoring for cardiovascular risk factors<sup>44,45</sup>.

Early and continuous medical follow-up minimizes the potential for missed clinical opportunities that contribute to poor outcomes including limb loss and death associated with the unpredictability of this time point<sup>46</sup>.

#### **Arterial Surveillance**

Given the considerable risk of restenosis and disease progression of the revascularized limb, regardless of the revascularization procedure performed, arterial surveillance at regular intervals can mitigate major complications. Current guidance documents recommend arterial surveillance at regular intervals to assess and reassess the intervention and to monitor disease progression<sup>45</sup>.

The use of DUS with or without ABI and TBI is a safe, efficient, and effective tool to detect subclinical abnormalities and/or to verify signs and symptoms related to revascularization failure and/or disease progression and is a core component to the arterial surveillance following revascularization for CLTI<sup>45</sup>.

**Recommendation 9:** Baseline surveillance and evaluation of restenosis, utilizing Doppler ultrasound (DUS) with hemodynamic testing such as the Ankle Brachial Index (ABI) or Toe Brachial Index (TBI) should occur early in the post revascularization period<sup>44</sup>.

#### The Role of Vascular Specialist

The post-revascularization vascular specialist follow-up monitors and assesses surgical/procedure site healing, hard-to-heal wound(s), infection, and ischemic pain and detects and treats early revascularization complications, failures, or restenosis. Medication compliance and ongoing support for therapeutic lifestyle interventions (e.g. smoking cessation) can also be completed during this post-procedure follow-up<sup>8,36,47</sup>.

Patients and their care providers should be aware of the frequency of follow up and the planned surveillance activities during the initial year following a revascularization procedure. Specific education regarding medication compliance, lifestyle modification, wound healing and the signs and symptoms of revascularization failure, restenosis and/or symptom deterioration, when to seek help, who to seek help from and when to return to hospital/emergency department for medical support are encouraged.

**\*Consensus Statement 6:** Following revascularization, vascular specialist follow-up should be completed within 30 days of discharge to assess recovery, wound healing, infection, ischemic pain, revascularization failure, or worsening symptoms, and to ensure compliance with medications and therapeutic lifestyle interventions.

#### The Role of the Primary Care Team

Reconnecting the patient with the Primary Care Team early in the post-revascularization period and throughout the recovery process is pivotal in identifying revascularization failure, restenosis, and/or symptomatic deterioration that requires prompt follow-up with the vascular specialist. The Primary Care Team is an excellent resource to support compliance with key medical and lifestyle treatments<sup>28</sup>.

In the subset of CLTI patients who do not have access to a Primary Care Team, efforts to connect these patients with a Primary Care Team will be an important aspect of discharge planning and to support the long-term management and optimization of chronic disease. During the early post-revascularization period, when a CLTI patient remains unattached to Primary Care, the responsibility for follow-up may fall to the vascular specialist.

**\*Consensus Statement 7:** Ongoing encounters with the patient's healthcare provider (e.g., Primary Care Team or Vascular Medicine Specialist, if available) should be encouraged before and after intervention as part of a strong surveillance program for comprehensive cardiovascular risk management.

#### Mid-term Follow-up (1 month to 12 months post revascularization)

At the discretion of the vascular specialist, ongoing follow-up through the first year may include clinical assessment with symptom testing, assessment of wound healing and arterial surveillance for the detection of revascularization failure and/or restenosis with additional follow-up by the multidisciplinary care team as required. The foundational surveillance during the first year following revascularization is a core component for the determination of baseline arterial health, to support long term patency of the revascularized vessel and to minimize future cardiovascular events and disease progression through aggressive secondary preventions strategies<sup>44,45</sup>.

**\*Consensus Statement 8:** All vascular programs should have standardized, intensive, and structured follow-up protocols available to every patient post-revascularization.

#### Long-term Surveillance Program (beyond 12 months post revascularization)

PAD, and the more devastating CLTI, is a chronic disease. Like other chronic diseases (e.g., cancer, chronic obstructive pulmonary disease, heart failure), a long-term surveillance program is a core component to mitigate the elevated risk for disease progression and recurrence<sup>45</sup>.

Although the imminent risk of revascularization failure decreases over time, yearly follow-up is recommended. Yearly follow up, in the absence of new signs and/or symptoms, utilizing clinical assessment and arterial surveillance (if required) allows for prompt identification of clinical issues and earlier revascularization when vessels experience impaired patency and/or disease progression<sup>45</sup>. In the presence of new signs or symptoms, more regular follow-up is required to determine the source of the issue and treat the vascular concern<sup>44</sup>.

Long term surveillance and follow-up is collaboratively provided by the vascular specialist and Health Care Provider (e.g., Primary Care Team, Cardiology, Endocrinology, General Internal Medicine, Vascular Medicine Specialist) with the knowledge, skills, and judgement to support the patient's longitudinal follow-up and clinical needs. Regardless of who is supporting the patient long term, continuous, aggressive secondary prevention for the prevention of future cardiovascular events, ongoing limb surveillance and supportive care by a multidisciplinary team is necessary<sup>44,48</sup>.

**Recommendation 10:** Ongoing follow-up should be part of a lifelong surveillance program and should include an annual clinical assessment and monitoring of patient compliance with key medical and lifestyle treatments for the reduction of MACE and MALE<sup>44</sup>.

### Conclusion

Timely access to care for patients with Chronic Limb Threatening Ischemia (CLTI) requires the coordination and expertise of many health care professionals. The clinical assessments and investigations with the associated timelines presented in the Chronic Limb Threatening Ischemia Clinical Practice Guidelines focus on the prompt identification, timely revascularization, and optimal medical management with ongoing follow-up to reduce MACE and MALE in patients with CLTI in Ontario.

The Chronic Limb Threatening Ischemia Guidelines reinforce the urgency of this work with the message "Time is Tissue, Tissue is Dignity". The recommendations and consensus statements emphasize to hospitals and health care providers the urgency and importance of this work. The new requirements for designated vascular programs and hospitals completing revascularization procedures further support this message with enhanced measurement and reporting. Ontario Health is committed to working with hospitals and health care providers to meet these timelines and requirements aiming to preserve limbs, reduce inequalities and improve the quality of life for all patients with CLTI in Ontario.

## **Appendix A – Physician Resources**

Below are additional resources and guidelines to support the early identification of Chronic Limb Threatening Ischemia and to prevent cardiovascular morbidity and limb loss, in patients with PAD.

- <u>Canadian Cardiovascular Society (CCS) 3-part webinar series (with accompanying slide deck)</u> <u>discussing the diagnosis, management, and revascularization of PAD. Peripheral Arterial Disease</u> <u>Webinar Series - Canadian Cardiovascular Society</u>
- <u>Canadian Cardiovascular Society (CCS)2022 Guidelines for PAD, Chapter 2 Management of</u> <u>Peripheral Arterial Disease - 2. Management of PAD - Canadian Cardiovascular Society</u>
- <u>2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management</u> of Lower Extremity Peripheral Artery disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.
- <u>European Society of Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management</u> of Asymptomatic Lower Limb Peripheral Artery Disease and Intermittent Claudication.

# **Appendix B: Abbreviations**

#### Table: List of Abbreviations and associated expanded forms

Abbreviation	Expanded Form
ABI	Ankle Brachial Index
ACC/AHA	American Cardiology Congress/American Heart Association
ASA	Acetylsalicylic Acid
BEST-CLI	Best Endovascular versus Best Surgical Therapy in Patients with CLTI
CCS	Canadian Cardiovascular Society
CIHI	Canadian Institute of Health Information
СКД	Chronic Kidney Disease
CLTI	Chronic Limb Threatening Ischemia
CO <sub>2</sub>	Carbon Dioxide
СТА	Computed Tomography Angiography
CVD	Cardiovascular Disease
DEC	Diabetes Education Centre
DM	Diabetes Mellitus
DUS	Lower Extremity Arterial Duplex Ultrasound
GFR	Glomerular Filtration Rate
GIM	General Internal Medicine
НВОТ	Hyperbaric Oxygen Therapy
LLP	Lower Limb Preservation
MACE	Major Adverse Cardiac Events
MALE	Major Adverse Limb Events
MRA	Magnetic Resonance Angiography
PAD	Peripheral Arterial Disease
PLAn	Patient risk, Limb severity and Anatomic pattern of disease
PVR	Pulsed Volume Recordings
ТАР	Target Arterial Path
ТВІ	Toe Brachial Index
WIfI	Wound, Ischemia and Foot Infection Classification System

# Appendix C: CIHI Project 380 Peripheral Artery Disease

In the province of Ontario, the CIHI Special Project 380 Peripheral Artery Disease identifies and differentiates the specific stages of PAD within the clinical administrative databases. CIHI Project 380 Peripheral Artery Disease utilizes the completion of a lower extremity revascularization procedure to track, measure and monitor the heterogeneous PAD patient population. The Ontario Ministry of Health mandates all hospitals in Ontario performing lower extremity revascularization procedures to complete Project 380.

The data from CIHI Project 380 is used to

- 1. Monitor health resource utilization across the various stages of PAD,
- 2. Monitor the vascular health outcomes across the various stages of PAD, and
- 3. Ensure treatments and procedures are aligned with best practice guidance for the various stages of PAD.

The standardized documentation of the stage of PAD must be consistent with the data collection of CIHI Project 380 Peripheral Artery Disease.

To define the specific stage of PAD in the patient's medical record, the most appropriate stage is used. CIHI Project 380 Peripheral Artery Disease uses the following descriptors to refine the stage of PAD.

- 1. Asymptomatic peripheral artery disease no prior intervention
- 2. Intermittent claudication
- 3. Asymptomatic peripheral artery disease primary assisted patency
- 4. Chronic limb-threating ischemia/Critical limb ischemia (CLTI/CLI)
- 5. Acute limb ischemia.

To enable the completion of the project field by Health Information Management and Coding teams, the vascular specialist (e.g., Vascular Interventional Radiologist or Vascular Surgeon) will document the specific stage of PAD in the patient record. This documentation can be included in various notes such as the Consultation Note, Operative Note, Procedural Note, and/or Discharge Summary.

# Appendix D: Example of a Referral to Vascular Services

#### **Hospital ABC**

Vascular and Endovascular Surgery Phone (123)456-7890 FAX: (123)456-7891

Please fax this form to: 123-456-7891

#### Referral for: ELECTIVE CONSULTATION

URGENT CONSULTATION

To: □ Dr. One BSc, DPharm, MD, FRCS
□ Dr. Two BHK, MD, RPVI, FRCS
□ Dr. Three BSc, PhD, FRCSC, RPVI
□ Next Available/On-Call Surgeon

Patient Information:	Name:
DoB:	OHIP:
Phone:	
Address:	

#### **Clinical History (symptoms) – mandatory for appointment triage:**

#### If imaging performed, please attach results.

<b>Clinical indication:</b>	Carotid Artery Stenosis – Symptomatic? Yes/No
	Suspected Aortic Aneurysm (AAA)/ Other aneurysm
	Peripheral Arterial Disease – claudication
	Chronic Limb Threatening Ischemia – rest pain/ hard-to-heal wound
	Diabetic Foot/Ulcers/Gangrene
	Thoracic Outlet Syndrome
	Varicose veins/ leg edema
	Arteriovenous (AV) Access
	Other:

#### Referring Physician (fill out completely)

Name:	Phone:	Fax:
Signature:	Billing number:	

### **Appendix E: Patient Resources**

Access safe, high-quality, health care information, advice, and referrals through <u>Health811</u> or by telephone at 811 (TTY:1-866-797-0007). This service is an accessible route to connect patients with the information and support they need but does not replace other touch points with the patient's healthcare provider.

Access to a wide variety of information on several topics including the following relevant topics specific to Chronic Limb Threatening Ischemia are available through the Health811 information portal.

- Peripheral Vascular Disease
- Smoking Cessation, programs, support and tools and resources
  - Smokers Helpline: a Canadian Cancer Society program that includes a 24-hour phone support service
  - Smoking Treatment for Ontario Patients (STOP) program: a Centre for Addiction and Mental Health (CAMH) program, funded by the Ontario Ministry of Health is a province wide initiative delivering smoking cessation treatment and counselling through local healthcare providers or online via the STOP on the Net program
  - o Local Pharmacy Services
- Registered Dietitian including access to free nutrition information
- Diabetes Education Centres
- Diabetic Foot and local Diabetes Foot Health program
- Diabetic Cardiovascular Disease
- Preventing and Living with Diabetes
- Healthy Choices (including healthy eating, food safety, hand washing and active living)

### Acknowledgements

### Working Group

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- **Chair**: Dr. Giuseppe Papia, Vascular Surgery, Sunnybrook Health Sciences Centre, Chair Vascular Surgery, University of Toronto
- **Executive Sponsor**: Dr. Varun Kapila, Provincial Physician Lead, Vascular, Ontario Heath, Vascular Surgery, William Osler Health Centre

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#### **Table 2: List of Working Group Members**

### **Secondary Reviewers**

#### Table 3: List of Secondary reviewers

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