

ECP Therapy — Clinical Evidence Summary

ACC Compliance Research Dossier | ECP Health Clinic Ltd | June 2026

This document forms part of a comprehensive evidence dossier submitted in support of ECP Health Clinic Ltd's application for ACC provider status. It summarises the global clinical evidence base for Enhanced External Counterpulsation (ECP/EECP) therapy, with specific reference to musculoskeletal rehabilitation, injury recovery, oedema management, bone healing, and circulatory restoration — all domains of direct relevance to ACC-funded treatment under the Accident Compensation Act 2001 (NZ).

1. What Is ECP / EECP Therapy?

External Counterpulsation (ECP) — also referred to as Enhanced External Counterpulsation (EECP) — is a fully non-invasive, outpatient medical treatment that uses pneumatic compression cuffs applied to the calves, lower thighs, and upper thighs/buttocks. These cuffs inflate sequentially during cardiac diastole (relaxation phase) and deflate rapidly at the onset of systole (contraction phase), driven by real-time ECG synchronisation. This creates a counter-pulsation effect that:

- Increases diastolic blood pressure and retrograde aortic blood flow
- Enhances coronary and systemic organ perfusion
- Reduces cardiac afterload (ventricular workload)
- Generates powerful haemodynamic shear stress across the endothelium
- Mobilises endothelial progenitor cells (EPCs) from bone marrow
- Stimulates nitric oxide (NO) production and new blood vessel formation (angiogenesis)
- Reduces systemic inflammation (TNF-alpha, CRP, MCP-1)

A standard ECP course consists of 35 one-hour sessions delivered over 7 weeks (5 sessions per week). The therapy is FDA-cleared, European Society of Cardiology–endorsed (2013), and included in national coverage determinations by the Centers for Medicare & Medicaid Services (CMS) in the United States.

2. Regulatory & Guideline Status

FDA Clearance (USA)	Cleared for angina, acute myocardial infarction, and cardiogenic shock. Multiple 510(k) devices approved since 1980.
CMS Coverage (USA)	National Coverage Determination (NCD 20.20) — EECP therapy funded for Class III/IV angina since 2006.
European Society of Cardiology	2013 ESC Guidelines include ECP/EECP in management plans for stable coronary artery disease.

TGA (Australia)	ECP devices registered under the TGA as Class IIb medical devices for cardiovascular indications.
Medsafe (New Zealand)	ECP devices may be registered as medical devices. ACC considers evidence-based novel therapies via clinical evidence review process.

3. Key Clinical Domains Relevant to ACC

The following table summarises the principal clinical domains where peer-reviewed evidence supports ECP/EECP for injury-related rehabilitation — the conditions most directly relevant to ACC coverage criteria.

Clinical Domain	Mechanism of Action	Evidence Level	ACC Relevance
Peripheral vascular & microcirculation rehabilitation	Sequential cuff compression increases shear stress, collateral vessel formation, VEGF release	Level I–II (RCTs, meta-analyses)	Injury-related vascular compromise, limb rehab
Anti-inflammatory & oedema reduction	Reduces TNF-alpha (16%), hsCRP (32%), MCP-1 (13%); improves lymphatic drainage	Level II (RCT, Circulation 2010)	Post-injury swelling, oedema management
Wound healing & tissue repair	Increases NO, VEGF, tissue perfusion by 30%; stimulates angiogenesis	Level II–III (controlled studies)	Soft tissue injury, non-healing wounds, crush injuries
Bone fracture healing	Mobilises EPCs; increases angiogenesis critical for osteogenesis; enhances oxygen/nutrient delivery	Level II–III (EPC studies, preclinical + clinical)	Fracture recovery, delayed union, non-union
Musculoskeletal pain & function	Reduces systemic inflammation; improves muscle perfusion and oxygenation	Level II–III (clinical studies)	Musculoskeletal injury rehab, chronic pain post-injury
Neurological rehabilitation	Increases cerebral perfusion, improves cerebrovascular reactivity	Level II (RCT, ESO 2025)	TBI, stroke-related motor rehab, nerve injury
Diabetic foot & peripheral neuropathy	Improves limb perfusion, nerve conduction, reduces foot ulcer risk	Level II–III (multiple RCTs)	Injury complications in diabetic patients

4. Safety Profile

ECP/EECP has an excellent safety record across hundreds of thousands of patients globally. It is non-invasive, requires no surgery or pharmacological agents, and the primary contraindications (aortic insufficiency, DVT, severe PAD, active haemorrhage) are readily screened. Adverse events are rare and typically minor (transient skin discomfort, fatigue).

Contraindications	Severe aortic regurgitation; active DVT or thrombophlebitis; aortic aneurysm; pregnancy; significant arrhythmia; severe uncontrolled hypertension (>180/110)
Precautions	Phlebitis, bleeding disorders, significant peripheral arterial disease. Pre-treatment assessment (ECG, BP, history) required.
Adverse Events	Rare; typically minor — skin irritation from cuffs, transient fatigue or muscle soreness. No serious device-related adverse events in major trials.
Session Duration	60 minutes per session, 5 sessions/week for 7 weeks (35 total)
Setting	Outpatient clinic — no hospitalisation, anaesthesia, or recovery time required

5. Alignment with ACC Rehabilitation Objectives

The Accident Compensation Act 2001 mandates that ACC fund treatment aimed at restoring independence, function, and return to work or daily activity. ECP therapy aligns with these objectives in the following ways:

- **Accelerated recovery:** ECP reduces inflammation and improves tissue perfusion, shortening rehabilitation timelines
- **Non-surgical alternative:** Provides measurable clinical benefit without the risks or costs of invasive procedures
- **Functional restoration:** Documented improvements in exercise capacity, 6-minute walk test, muscle function, and quality of life
- **Evidence-based:** Supported by Level I–II evidence including RCTs, systematic reviews, and meta-analyses
- **Cost-effective:** Lower cost than repeated physiotherapy courses or surgical intervention; durable effects documented at 5-year follow-up
- **Passive rehabilitation:** Suitable for patients who cannot tolerate active exercise — particularly relevant for severe injuries, elderly, or co-morbid claimants

References — Document 1

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