NECA-Health Technology Reassessment Project

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Health Technology Reassessment Report 2020

# Autologous Bone Marrow Stem Cell Treatment

# - in patient with Critical Limb Ischemia -

## Injection of Bone Marrow collected after the G-CSF Formulation at Ischemic Area

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# Summary Statement

## Background

One of the most severe clinical manifestations of peripheral arterial disease(PAD), critical limb ischemia(CLI) is characterized by marked obstruction of the arteries or reduction of blood flow to the lower extremities to progress to necrosis of tissues, leading to amputation of lower limb or foot in severe cases.

Meanwhile, 'Autologous Bone Marrow Stem Cell Treatment in patient with Critical Limb Ischemia' was registered in 2012, and publicly announced (by the Ministry of Health and Welfare as Public Announcement #2013-114, Feb. 28, 2013) as a new technology as a non-benefit item. As one of two publicly announced autologous bone marrow stem cell treatment methods in patient with critical limb ischemia, 'Injection of Bone Marrow collected after the G-CSF Formulation at Ischemic Area (SZ087)' was brought to the 2nd meeting of Health Technology Reassessment Committee in 2020, followed by the safety and effectiveness review in the competent sub-committee.

Comprised of 8 different sub-committee members, the sub-committee held three different review meetings starting August 2020 and ended December of the same year. The final screening for conclusion of result and grading of the technology was held in the 1st Health Technology Reassessment Committee in 2021.

## Methodology

Systematic literature review(SLR) was conducted for assessment of safety and effectiveness of 'Injection of Bone Marrow collected after the G-CSF Formulation at Ischemic Area' in patient with critical limb ischemia. Three different international literature databases and five different domestic literature databases were referred to in selection of literatures to be reviewed, under literature inclusion and exclusion criteria and by two separate reviewers.

## Result

Out of 5,871 (4,191 international, 1,680 domestic) literatures, 3,366 different literatures, duplicate contents excluded, were reviewed. None of the reviewed literatures were selected according to the pre-determined inclusion and exclusion criteria.

## Conclusion and Suggestion

According to the systematic literature review(SLR) on Injection of Bone Marrow collected after the G-CSF Formulation at Ischemic Area, no previously composed literature was selected under the pre-determined PICO and the RCT.

With no previously composed literature selected as a documentary evidence, the sub-committee has concluded that the safety and effectiveness of the technology cannot be determined.

Therefore, the Health Technology Reassessment Committee has screened for the conclusion that, with no previously composed literature selected as a documentary evidence, the safety and effectiveness of the technology cannot be determined and that with similarity to 'Autologous Bone Marrow Stem Cell Treatment - in patient with Critical Limb Ischemia - Injection of Centrifuged Bone Marrow at Ischemic Area,' the technology is 'not recommended' (Recommendation Grade II) (Jan. 15, 2021).

## Keywords

Critical Limb Ischemia, Autologous Bone Marrow Stem Cell Treatment, mononuclear cell, Granulocyte-Colony Stimulating Factor (G-CSF)