

## 変更対比表

作成年月日：2023年2月24日

治療課題名：『自家末梢血 CD34 陽性細胞移植による下肢血管再生療法（治療）』

以下に、「1-5 再生医療等を受ける者に対する説明文書及び同意文書の様式」（インバウンド用同意説明文書英語版/For Patient Reference）における修正箇所について修正・追加を下線、削除を、二重取消線として示す。

訂正箇所	Ver. 2.0	Ver. 2.1	変更理由
フッター	Shonan Kamakura General Hospital <del>Ver.2.0</del> Date of Creation: <del>January 20, 2023</del>	Shonan Kamakura General Hospital <u>Ver.2.1</u> Date of Creation: <u>February 24, 2023</u>	版の更新
p.24 7. Potential Health Hazards	(omitted above) Please note that the following cases are not eligible for compensation. <del>The treatment(s) will be covered by normal health insurance and you will be required to pay the co-payment.</del> ● If the health problem turns out to be unrelated to this treatment. ● If the health hazard was caused by your intentional or negligent act. ● If cell transplantation is not effective. (omitted below)	(omitted above) Please note that the following cases are not eligible for compensation: ● If the health problem turns out to be unrelated to this treatment. ● If the health hazard was caused by your intentional or negligent act. ● If cell transplantation is not effective. (omitted below)	誤記修正
p.26 10. Cost of Treatment	By this treatment, the following expenses will be incurred: hospitalization expenses during the treatment period after the start date of G-CSF administration; drug, medical material, and laboratory expenses during G-CSF administration, apheresis, CD34-positive cell isolation, and cell transplantation; hospitalization expenses for post-transplant examinations* during the observation period (1 day, 7 days, and 24 weeks) and laboratory expenses, etc. The standard co-payment amount is approximately 6.6 million yen <del>without</del> consumption tax. The patient	By this treatment, the following expenses will be incurred: hospitalization expenses during the treatment period after the start date of G-CSF administration; drug, medical material, and laboratory expenses during G-CSF administration, apheresis, CD34-positive cell isolation, and cell transplantation; hospitalization expenses for post-transplant examinations* during the observation period (1 day, 7 days, and 24 weeks) and laboratory expenses, <u>etc.</u> The standard co-payment amount is approximately 6.6 million yen <u>with</u> consumption tax (the same	治療費以外の加算があることが分かるように、検査費の次に” etc”を追記修正  費用を消費税込みの表

	<p>will also be responsible for the cost of extra bedding, as well as any other expenses incurred at his or her request.</p> <p>If you wish to have a pre-registration examination at our hospital, the maximum amount will be <del>200,000 yen</del> for the examination within 16 weeks prior to the registration. The maximum amount will be <del>80,000 yen</del> for the examination within 2 weeks prior to the registration. In addition, hospitalization expenses for the number of days required for the examination will be charged.</p> <p>※The day of transplantation is considered day 0.</p>	<p><u>hereinafter</u>). The patient will also be responsible for the cost of extra bedding, as well as any other expenses incurred at his or her request.</p> <p>If you wish to have a pre-registration examination at our hospital, the maximum amount will be <u>220,000 yen</u> for the examination within 16 weeks prior to the registration. The maximum amount will be <u>88,000 yen</u> for the examination within 2 weeks prior to the registration. In addition, hospitalization expenses for the number of days required for the examination will be charged.</p> <p>※The day of transplantation is considered day 0.</p>	<p>記に修正 また、上記の表記修正前に、消費税抜き費用を660万円から600万円に誤記修正</p>
--	--	---	--

以上