INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH

September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1753-P,
P.O. Box 8010,
Baltimore, MD 21244-1850

Re: CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P)

Dear Administrator Brooks-LaSure,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our support for the Proposed OPPS APC-Specific Policy: Stromal Vascular Fraction (SVF) Therapy, which eliminates the reimbursement for adipose-derived SVF for osteoarthritis—an unproven treatment. The ISSCR is the leading professional organization of stem cell researchers and represents more than 4,000 members in the United States and around the world. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. We are concerned with the premature commercialization of unproven cellular therapies because it puts patients at risk and wastes public and patient resources that should go toward treatments approved by regulators and proven safe and effective.

The clinical use of adipose-derived SVF for osteoarthritis is speculative and needs to be evaluated in well-controlled clinical trials overseen by the U.S. Food and Drug Administration (FDA) to determine whether it is a safe and effective therapy. So far, the clinical trials that have been performed using SVF have tended to be early-stage trials that were not designed to test efficacy – either uncontrolled or with small numbers of patients. Also, some of the trials showed little or no sign of efficacy. There remain no indications for which SVF has been proven to be safe and effective in well-controlled clinical trials.

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We are concerned that the premature reimbursement of SVF for osteoarthritis may get abused by unscrupulous businesses seeking to profit from consumer enthusiasm for stem cell research and regenerative medicine. The FDA has issued multiple warnings about unproven cellular therapies and regenerative medicines because they offer no proven clinical benefits and may harm patients. These businesses have used the ClinicalTrials.gov database to recruit patients by implying that a listing in a government database of clinical trials suggests rigor and legitimacy and in some cases by suggesting this reflects regulatory approval. These businesses may use CMS coverage for their treatments as a token of legitimacy for recruiting patients and persuading private insurers to offer coverage. At best, the products they market are unlikely to provide any benefit to patients. Moreover, we have learned that businesses that are willing to ignore FDA marketing regulations are often also willing to ignore regulations related to good manufacturing processes. Unproven stem cell therapy products have seriously injured patients, causing tumor growth, blindness, and bacterial infections. Reimbursement for unproven and unapproved therapies must be halted as it places unnecessary economic burdens on health systems and patients.

Thank you for considering our views on the Proposed OPPS APC-Specific Policy: Stromal Vascular Fraction (SVF) Therapy. If the ISSCR can clarify any of these views or be of assistance, please contact Eric Anthony, ISSCR's Director of Policy at eanthony@isscr.org.

Sincerely,

Melissa H. Little
President, ISSCR
Murdoch Children's Research Institute and
University of Melbourne, Australia