ARM and NAMCP Publish Recommendations to Increase Patient Access in Joint Study, "Roadmap for Navigating Cell and Gene Therapy Value Demonstration and Reimbursement in U.S. Managed Care"

WASHINGTON, D.C. – September 24, 2019 – The Alliance for Regenerative Medicine (ARM) and the National Association of Managed Care Physicians (NAMCP) Medical Directors Institute announced today the joint release of their recent study of medical director and manufacturer perspectives on value demonstration and reimbursement for cell- and gene-based regenerative and advanced therapies.

The study, entitled "Roadmap for Navigating Cell and Gene Therapy Value Demonstration and Reimbursement in U.S. Managed Care," characterizes step-by-step considerations for achieving appropriate patient access to transformative and potentially curative therapies in the U.S. managed care setting. The findings identify key issues relevant to value demonstration and access to potentially curative therapies at a pivotal time for the industry, as several products have reached the market, with dozens more in late-stage clinical trials.

"The initial wave of cell and gene therapies has launched into an environment that was not built with transformative or curative therapies in mind," said Eric Faulkner, Vice President, Precision and Transformative Medicine at Evidera and lead author for the publication. "It's crucial for payers, providers, patients, and other stakeholders to align on expectations on value demonstration to ensure sustainable access."

"In the next two to three years, the sector expects the number of marketed cell and gene therapies to more than triple," said Janet Lambert, CEO for the Alliance for Regenerative Medicine. "We will improve patient lives if we ensure patients have timely access to these treatments and value assessment and reimbursement processes have been structured with these unique therapies in mind."

"Appropriate reimbursement and access to transformative therapies is critical to constantly improve managed care practice, appropriate patient access and outcomes. This effort is one step to achieving that goal by identifying and acknowledging the key acceptance requirements and stakeholder perspectives as these therapies enter the marketplace," said Bill Williams, MD, Executive Vice President of the NAMCP Medical Directors Institute.

The study concludes with several key learnings for therapeutic developers and payers:

- **Reducing barriers to coverage will be critical for equitable patient access to cell and gene therapies.** Without a clear and timely route to coverage for cell and gene therapies, manufacturers and investors may be prompted to reconsider investment in this promising area that has not only potential to transform patient care, but also, ultimately, the broader healthcare system.
- **Improving stakeholder alignment on evidence requirements and a value framework for cell and gene therapies is key to support more rapid coverage and access decisions.**

As we move into this new era of evidence-based medicine, it will be important for regulators, HTA agencies, payers, and manufacturers to align with this more iterative and continuous evidence-development environment and clarify their requirements.

- **Lack of appropriate fit into existing coding and payment systems creates significant risks for provider adoption and patient access.** As more cell and gene therapies enter the marketplace, it will be critical to develop replicable coding and payment models that (a) do not place providers at risk of financial loss, b) are predictable and avoid cash flow impacts of high cost, single-payment scenarios, and (c) are affordable to the system.
- **Cell and gene therapy manufacturers must think comprehensively and not take anything for granted in developing a value demonstration strategy.**
- **It is critical for commercial payers to actively engage in solutions for making truly transformative therapies available to patients in an affordable manner.**

The study results are available to at the following link:

http://www.namcp.org/journals/ARMMonograph2019.pdf

About The Alliance for Regenerative Medicine

The Alliance for Regenerative Medicine (ARM) is an international multi-stakeholder advocacy organization that promotes legislative, regulatory and reimbursement initiatives necessary to facilitate access to life-giving advances in regenerative medicine worldwide. ARM also works to increase public understanding of the field and its potential to transform human healthcare, providing business development and investor outreach services to support the growth of its member companies and research organizations. Prior to the formation of ARM in 2009, there was no advocacy organization operating in Washington, D.C. to specifically represent the interests of the companies, research institutions, investors and patient groups that comprise the entire regenerative medicine community. Today, ARM has more than 350 members and is the leading global advocacy organization in this field. To learn more about ARM or to become a member, visit http://www.alliancerm.org.

About the NAMCP Medical Directors Institute

The NAMCP Medical Directors Institute is a non-profit membership association, which was established to provide tools, education, and resources to medical directors, practicing physicians, and other healthcare professionals. NAMCP Medical Directors Institute's mission is to help Medical Directors from purchasers, health plans, and provider systems make effective and informed decisions, respond to opportunities and challenges in managed care, while helping improve healthcare outcomes, and ultimately the lives of members and patients. To learn more about the NAMCP Medical Directors Institute or to become a member, visit http://www.namcp.org.