



The Alliance for Regenerative Medicine (ARM) is the preeminent global advocate for regenerative and advanced therapies. ARM fosters research, development, investment, and commercialization of transformational treatments and cures for patients worldwide.

By leveraging the expertise of its membership, ARM empowers multiple stakeholders to promote legislative, regulatory, and public understanding of, and support for, this expanding field.



The Value of New Cell and Gene Therapiés

The regenerative medicine and advanced therapies sector is truly the next frontier for patients, developing revolutionary, durable treatments, and potential cures for some of humankind's most devastating diseases – many currently untreatable via conventional treatments.

These products are intended to augment, repair, replace, or regenerate organs, tissues, cells, genes, and metabolic processes in the body. This sector holds the promise of addressing many currently unmet medical needs, and represents a major paradigm shift in medicine – treating the root causes of disease and disorders to stop or even reverse progression.



- It's critical the program is modified to accommodate new and life-saving treatments to enable patient access
- ARM has previously expressed concerns about CMS's application of newness and substantial clinical improvement criteria
- Clinical trial size is not an issue for FDA approval and should not be an issue for CMS
- Payment Amount disadvantages many hospitals and impedes access
- Frequency The NTAP process should mirror outpatient setting
- Post NTAP Should CMS establish separate and distinct MS-DRGs by class of therapies?



- CMS demonstrated support for the NTAP program and willingness to adapt it to new innovative technologies
- CMS seems open to possible increased payments including a new DRG
- CMS expressed support for a 1.0 CCR
- ARM still developing specific recommendations on these and other issues
- It is critical that the program be adapted to support new innovations; CMS clearly wants and needs to hear from all stakeholders about the importance of these therapies





