



POLICY & BIOELECTRONIC MEDICINE: DELIVERING VALUE FOR PATIENTS, HEALTH SYSTEMS, AND SOCIETY



Bioelectronic medicine is poised to play a central, growing role in the future of healthcare. This innovative field already provides critical benefits to patients, health systems, and society—but this is just the beginning of what’s possible. With the right policy support, the field can deliver important new treatments in areas of unmet need, advance care for costly chronic diseases, improve health outcomes, and realize long-term value.

However, targeted policy action is needed to realize this potential. Regulators, payers, researchers, and health policy experts now have an opportunity to tap into and expand the field’s unique advantages—paving the way for more effective, efficient healthcare.

THE PROVEN VALUE & FUTURE POTENTIAL OF BIOELECTRONIC MEDICINE

Bioelectronic medicine is a rapidly growing field that uses targeted electrical signals to harness the body's natural mechanisms to diagnose, treat, and prevent a range of diseases. It includes widely known devices like pacemakers, but also a growing number of applications for diseases where current treatments fall short for some patients, such as Parkinson's, major depressive disorder, incontinence, epilepsy, chronic pain, uncontrolled hypertension, and others.

The field offers a number of important advantages:

- **Saving lives and improving health outcomes.** Common applications like pacemakers, vagus nerve stimulators, and spinal cord stimulators are already used by millions of patients—and proven to improve health outcomes. Research has found that vagus nerve stimulation can reduce epileptic seizures by 20-50%, implanted cardiac devices can reduce the risk of mortality by 40%, and spinal cord stimulation can achieve relief for chronic pain in 60-80% of cases.^{1,2,3}
- **Delivering value for patients and health systems.** By improving care for chronic conditions, bioelectronic medicine can help to avoid costly ER usage and hospitalizations. For example, atrial fibrillation ablation has been found to reduce arrhythmic hospitalization by 56% and hospitalization for heart failure by 43%, realizing huge cost savings for patients and payers.⁴
- **Meeting patients' needs in challenging disease areas.** Bioelectronic medicine researchers are steadily driving advances on some of the greatest challenges in healthcare, including treatment-resistant depression,^{5,6} PTSD,⁷ chronic pain,⁸ and Parkinson's disease.⁹ Bioelectronic medicine has the potential to address the immense unmet need in these areas, offering hope to patients and families.
- **A fast-growing healthcare field.** Bioelectronic medicine attracts investment, creates jobs, and delivers benefits to the healthcare industry. This market is projected to more than double from \$22.6 billion in 2019 to more than \$60 billion in 2029.¹⁰

CURRENT APPLICATIONS AND FUTURE POTENTIAL

Bioelectronic medicine includes a broad range of disease areas and devices spread across a number of sub-fields. The most well-developed of these is cardiac rhythm management, which addresses heart rhythm disorders with devices like pacemakers and includes electrophysiology, focusing on catheter-based approaches.

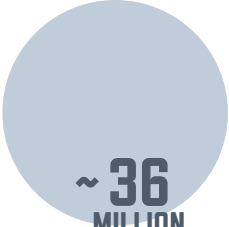
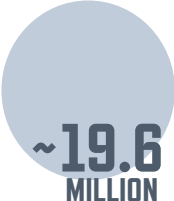



Neuromodulation is a relatively newer field that focuses on stimulating specific nerves in the central nervous system or peripheral nervous system. These include applications for deep brain stimulation, spinal cord stimulation, vagus nerve stimulation, and sacral nerve stimulation. Bioelectronic medicine also includes cochlear and retinal implants.

SUB-FIELDS OF BIOELECTRONIC MEDICINE

Sub-Field	Examples of Devices	Examples of Diseases
Cardiac Rhythm Management	Pacemakers, implantable cardioverter defibrillators, catheter-based treatments for arrhythmias	Bradycardia, tachycardia, heart failure, atrial fibrillation
Central Nervous System Stimulation	Devices that stimulate the spinal cord or specific regions of the brain	Chronic pain, treatment-resistant epilepsy, Parkinson's, depression
Peripheral Nervous System Stimulation	Devices that stimulate the vagus nerve or sacral nerve	Rheumatoid arthritis, IBD, overactive bladder, urinary incontinence
Cochlear and Retinal Implants	Implants that capture, digitize, and transmit sound or visual information	Hearing loss/impairment, retinal degeneration

POTENTIAL GROWTH AREAS FOR BIOELECTRONIC MEDICINE

Bioelectronic medicine also has potential to grow in areas where existing pharmaceutical and surgical treatments have only limited efficacy or significant side effects, such as high-impact chronic pain, refractory major depressive disorder, and uncontrolled hypertension.

DISEASE AREA	NUMBER OF PATIENTS (U.S.)	BIOELECTRONIC MEDICINE POTENTIAL ROLE
Uncontrolled hypertension¹¹	 ~36 MILLION	Option in cases where other treatments fail or with adherence challenges
High-impact chronic pain¹²	 ~19.6 MILLION	Alternative to opioid treatment
Atrial fibrillation¹³	 ~2.7-6.1 MILLION	Option in cases where medication fails
Refractory major depressive disorder¹⁴	 ~4 MILLION	Adjunct to pharmaceutical treatment
Parkinson's disease¹⁵	 ~1 MILLION	Option to address symptoms when not adequately controlled by medication

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POLICY ACTIONS TO SUPPORT BIOELECTRONIC MEDICINE

While bioelectronic medicine is already achieving important progress, greater policy support is needed to accelerate real-world benefits. Far more can be accomplished if policymakers take action to facilitate research, streamline regulatory and reimbursement pathways, and facilitate adoption for those who stand to benefit most.

The Alliance for Advancing Bioelectronic Medicine (AABM) is a new multi-sector coalition dedicated to fostering growth and facilitating connections across the emerging field of bioelectronic medicine.

We are eager to work with policy leaders, regulators, payers, healthcare economics and outcomes research (HEOR) organizations, and other stakeholders to drive progress.



Several policy actions are key:

- **Fund basic science and clinical research.**

Policymakers and government research institutions can provide funding or incentives to speed basic science, clinical research, and progress towards new treatments. For example, the NIH's Stimulating Peripheral Activity to Relieve Conditions (SPARC) program works to map therapeutic targets for neuromodulation, including policy priorities like chronic pain and opioid addiction.¹⁶

- **Streamline regulatory pathways and consider the patient voice.**

Innovators in the field have expressed the need for additional guidance from regulators about how to best navigate regulatory pathways, especially considering that many of these companies are relatively small and must use resources efficiently. Regulators should also consider the voice of patients and the potential for innovative treatments to address unmet need in challenging disease areas.

- **Analyze cost savings.**

Payers and HEOR organizations can analyze the health outcomes and cost savings of bioelectronic medicine applications, particularly in chronic diseases with high levels of unmet medical need and costly current treatments. This will provide the basis for wider adoption and ultimately greater value for health systems.

- **Integrate into billing codes and treatment guidelines.**

Payers can include bioelectronic medicine applications in billing codes and explore inclusion in treatment guidelines, especially considering the potential for cost savings.

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ENDNOTES

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