

PBM's Regulatory Labyrinth

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If photobiomodulation (PBM) is so effective, why is it not already part of mainstream medicine?

That is the question we all ask, and are asked, as we mark the 55th anniversary of PBM's discovery.

As with anything in medical science, the answer is complicated.

For those not familiar with PBM, it is a low-intensity, visible and near-infrared light therapy which is applied to joints, injuries, and the nerves that supply them. The effects are analgesic, anti-inflammatory, and regenerative (the light improves the rate of tissue healing). PBM therapy is usually applied multiple times a week for several weeks, which leads to substantial relief.

There is significant evidence from more than 100 million patient treatments, 800 clinical trials, and 9,000 published papers showing PBM therapy is effective for managing musculoskeletal and neuropathic pain. The treatments are safe and noninvasive. It is recommended for preventing oral mucositis and other side effects from chemotherapy.

The challenge for making PBM a mainstream medical therapeutic intervention starts with terminology. When Dr. Endre Mester discovered the effects of lasers on mice he named it "biostimulation." Since then, approximately a hundred different terms have been used to describe PBM. Extensive

efforts to achieve scientific consensus for using "Photobiomodulation" has not clarified the research landscape. Delving into PBM papers in the National Institutes of Health (NIH) National Library of Medicine (NLM) requires grappling with this terminological Tower of Babel.

This is why, in 2019, the Library of Congress Congressional Research Service (CRS) declared there was only limited published research on PBM as the report's author only scanned for PBM.¹

Wikipedia doesn't even have a PBM page, retaining its embrace of the term Low-Level Laser Therapy (LLLT).

Just as the term PBM is gaining currency, along comes "Red Light Therapy." Amazon and other consumer Web sites are awash in poorly made products within and outside the U.S. that assert they do everything medical grade devices do, but clearly do not.

Reputation is the second major challenge for PBM. The Red Light Therapy (RLT) market is disappointing and confusing consumers. Most devices deliver only a fraction of their promised dosage. Many break down after minimal use.

RLT devices gain U.S. Food and Drug Administration (FDA) clearance by being "substantially equivalent to another (similar) legally marketed device." RLT device manufacturers make elaborate and outlandish claims, then offer legal

disclaimers buried deep in their literature that their product has not been evaluated by the FDA and are “not intended to diagnose, treat, cure, or prevent any disease or health condition.”

It is no wonder that skepticism remains a major mountain to overcome.

PBM’s path to mainstream acceptance was hampered by it being discovered in a laboratory located in Budapest, Hungary. Research generated behind the “Iron Curtain” was not readily available to the West until 1990. There were general concerns about the integrity and methodology of research conducted in the Eastern Bloc. By 1991, the NIH NLM began vetting and curating PBM research conducted by Mester and his colleagues. So, it was almost a quarter of a century after its original discovery that PBM, known at that time as LLLT, became known to the Western scientific and medical community.

Today, all of us involved in the “PBM Movement” have our commitment validated with a steady stream of evidence that this medical treatment saves and improves lives. However, anecdotal evidence does little to move PBM toward becoming a mainstream treatment.

FOOD & DRUG ADMINISTRATION

The FDA regulates the manufacturing and selling of PBM devices, but not their use. This means once a PBM device is purchased, the owners (including medical professionals) can use it any way they want and make any claim they wish. It is therefore important that the FDA’s clearance of PBM devices provides accurate information to the marketplace.

The challenge is that the FDA’s “ILY” product code^{2,3} mischaracterizes PBM devices as “providing topical heating.” PBM devices are classified as Class II (special controls). They are exempt from premarket notification procedures (510(k) submission and review) “when it is an infrared

therapeutic heating lamp.” The FDA states the light wavelength range of these devices is approximately 700 nanometers to 50,000 nanometers.

There are many problems with FDA’s “ILY” designation (Regulation Number 890.5500). PBM does not use heat. PBM uses red to near-infrared light (600-1100 nanometers).⁴

Being a “non-heating” heating lamp under ILY provides the opening for most consumer “red light” products, as well as medical-grade devices, to enter the market as temporarily relieving pain. However, it severely limits the official use of PBM for treating serious medical conditions.

Recently, the FDA came up with a more accurate “NHN” designation which requires 510(k) submission.

A LASER (Light Amplification by Stimulated Emission of Radiation) based device having coherence, collimated and typically monochromatic radiation. This device emits energy in the infrared or other wavelengths, provides non-heating and non-thermal effect, and is indicated for adjunctive use in pain therapy or related indication. It does not provide therapeutic topical heating. The classification regulation for infrared lamps describes a device that emits energy in the infrared wavelength to provide topical heating and this is not limited to adjunctive use.⁵

The problem with “NHN” is the continued limitation to only treating pain. The other problem is that PBM devices are moving increasingly to light-emitting-diode (LED)-based dosage delivery.

The FDA finally recognized PBM being delivered by LED in their “PLH” designation, but only as an “Orthodontic LED Accessory” for “applying light energy to the tissue surrounding tooth roots for a photobiomodulation effect.”⁶ Another new PBM designation is “IOB” for treating neurological conditions.⁷ These codes show FDA is moving

away from LLLT to the preferred PBM. Both PLH and IOB codes require 510(k) submission.

FDA consideration of a separate broad, all-inclusive, and accurate PBM code has been in the works. Starting in July 2019, the PBM Foundation, along with industry partners, supported finalizing this separate PBM code. The new FDA Administrator may provide needed momentum.

Under existing FDA codes, and under a proposed PBM code, officially and legally treating the conditions where PBM has proven its efficacy may require the establishment of new intended uses. This would be costly and time-consuming.

Key to verifying intended uses has been obtaining FDA comments and approval before proceeding with clinical trials. FDA has rejected evidence from “unblessed” clinical trials because they were deemed inadequately designed, poorly controlled, and their “confirmatory evidence” ruled invalid.

MEDICARE

Reimbursement may be the pathway to mainstream PBM use. When PBM use is limited to self-paying patients paying full fair price, patients with Medicaid and insurance can be denied PBM medical benefits.

Private practices and wellness centers have attracted increasing numbers of patients who are willing to pay completely out-of-pocket for the PBM benefit. Celebrities and digital billionaires have acquired PBM units for their anti-aging “health span” regimes. Major cancer centers are absorbing patient costs to provide life-saving treatments based upon the recommendations issued from the Multinational Association of Supportive Care in Cancer (MASCC).⁸ U.S. Veteran Health Centers are slowly incorporating PBM into their physical therapy and neurological units.⁹

For most people, Medicare and private insurance companies need to cover PBM treatments

before they become routine offerings. Blue Cross Blue Shield Association is beginning to cover PBM for preventing the side effects of cancer chemotherapy, as outlined in the MASCC recommendations.^{10,11}

Medicare is one focus of the PBM Foundation and its advocacy and stakeholder partners. The Centers for Medicare and Medicaid Services (CMS) are establishing a separate reimbursement code for chronic pain management.^{12,13} Adding PBM to this code may speed the process.

The challenge is overcoming CMS’s 2006 decision against Anodyne (CAG-00291N).¹⁴ In 2005, FDA’s Manufacturer and User Facility Device Experience (MAUDE) adverse event surveillance system revealed 46 patients with burns after using Anodyne’s Low-Level Laser Therapy (LLLT) devices. CMS initiated a National Coverage Determination (NCD) to determine whether there was sufficient evidence to conclude that infrared devices (LLLT) were “reasonable and necessary for treatment of Medicare beneficiaries for diabetic and non-diabetic peripheral neuropathy, wounds and ulcers, and similar related conditions.”

CMS’s review, which included public comment, concluded:

There are no indications for which these devices have been demonstrated to have any therapeutic effect. The device and any related accessories will be denied as not medically reasonable and necessary.

CMS has determined that there is sufficient evidence to conclude that the use of infrared devices is not reasonable and necessary for treatment of Medicare beneficiaries for diabetic and non-diabetic peripheral sensory neuropathy, wounds and ulcers, and similar related conditions, including symptoms such as pain arising from these conditions. Therefore, we are issuing the following National Coverage Determination.

The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy (MIRE), is not covered for the treatment, including symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of skin and/or subcutaneous tissues in Medicare beneficiaries.

CMS was especially damaging in its critique of the evidence and research methodology:

Although there have been many published reports of clinical trials of infrared therapies... most have methodologic shortcomings that to varying degree weaken the confidence that can reasonably be accorded to many of their authors' stated conclusions. In many instances the conclusions offered by the authors cannot be accepted at face value, and we are thus unable to confidently reject alternative explanations for the same results. In some instances, the trial methodology is so inadequate that we can reach no robust conclusion about the trial results. External technology reviews and evidence based guidelines have, when infrared therapy is mentioned at all, given it low ratings.

Most worrisome was the lack of professional support during the 2006 public comment process:

CMS received and considered comments favoring coverage from two national professional organizations of laser therapy; CMS did not receive any comments from the national professional medical and surgical societies more classically associated with the care of wounds, neuropathy, and their underlying medical conditions, e.g., diabetes. The published evidence-based guidelines for these conditions do not include infrared therapy or designate it as ancillary therapy with a minimal evidence base.

In the wake of the Anodyne decision, leaders of the PBM movement, scientists, policy officials, researchers, and practitioners convened a series of meetings. The goal was to assess the state of PBM research, its acceptance, and options for moving forward.

In September 2015, the Optical Society of America (OSA) hosted the PBM Global Incubator attended by 75 experts. The group determined that the chaotic state of PBM science was like the "Wild West." Until clinical standards were enforced, and scientific discipline established, PBM would be ignored by mainstream medical professionals, especially major national associations.

In October 2017, the working group from the OSA meeting developed a strategic framework for moving forward. This drew upon the ongoing discussions arising from the OSA meeting. It was decided to form the nonprofit PBM Foundation to coordinate professionalizing the PBM movement, develop compelling messaging, and direct engagement with medical innovators, health policy officials, and stakeholders. Another component was to establish a Center of Excellence in PBM to develop best practices in education, research, and technology verification. The Center of Excellence opened at Shepherd University in Shepherdstown, West Virginia, in the spring of 2022.

PBM's documented impacts, including energizing the subatomic mechanisms within cellular mitochondria, the photoactivation of latent transforming growth factor, and other molecular mechanisms¹⁵ completely redefines the future of healthcare. Leaders of the PBM movement realize that this revolutionary technology shatters numerous medical paradigms.

It is a crusade worthy of the 21st century.

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