Unproven Therapies

AMERICAN DIABETES ASSOCIATION

Advances in modern medicine are achieved through basic and clinical research using well-established principles of experimentation. These include controlled clinical trials to assess the efficacy and safety of novel diagnostic and therapeutic techniques. Publication of results and their replication in additional experiments performed by other independent scientists are necessary components of the process by which efficacy and safety are documented. The American Diabetes Association, the National Institutes of Health, and other health-related organizations sponsor diabetes-related research that adheres to these standards.

In contrast, unproven therapies tend to share certain characteristics:

- They tend to be developed and promoted in isolation from established scientific facilities and associations, and their developers and proponents generally do not possess strong clinical or scientific credentials.
- The rationales for these therapies often contain misapplication of data from the scientific literature.
- Proposers often provide exaggerated or unrealistic claims about these modalities.
- These therapies often have the potential to be financially profitable to those who have developed, promoted, or endorsed them.
- They are generally communicated outside regular channels of scientific and clinical communications, and the details of the therapies are often secretive.
- Their proponents sometimes discourage or refuse consultation with or review by reputable physicians or scientists.
- Their developers and promoters often claim that a medical or scientific "conspiracy" has been convened against them.

The American Diabetes Association evaluates questionable diagnostic and therapeutic modalities, reviewing what is known about:

- The effectiveness of the modalities, including the number and quality of studies performed;
- The degree to which independent validation has been accomplished;
- The potential risk of harm to patients associated with the modalities.

The American Diabetes Association uses a combination of effectiveness research and expert consensus to characterize therapeutic modalities as either:

- Clearly effective,
- Somewhat/sometimes effective or effective for certain categories of patients,
- Unknown/unproven but possibly promising, or
- Clearly ineffective.

Operationally, the American Diabetes Association considers a diagnostic or therapeutic modality to have established safety and efficacy when it has been:

- Approved for use by the FDA, or
- Supported by data obtained in at least two independent, well-controlled studies that have been published in peer-reviewed scientific publications, or
- Endorsed or recommended by the American Diabetes Association's Professional Practice Committee, or
- Endorsed by a relevant or appropriate medical specialty organization,

And the modality has been endorsed or recommended by a scientifically developed practice guideline under the auspices of a recognized authority in the field and subsequently affirmed and approved by the American Diabetes Association's Professional Practice Committee.

New and innovative, but unproven, diagnostic and therapeutic measures may be provided for patients in two circumstances: *1*) as part of an investigational trial that conforms to the U.S. Department of Health and Human Services regulations for protection of human research subjects and has been approved by a duly constituted review board or clinical investigations committee of an institution approved to conduct such research; and *2*) when a duly constituted review board or clinical investigations committee of an institution approved to conduct such clinical trials approves such use under provisions of compassionate use.

In general, patients should not be expected to pay for additional elements of care required by the protocol in the first circumstance and should not pay more than the usual institutional costs or usual professional fees associated with the provision of such measures in the second circumstance.

Approved October 1993.