

Resources & Information

Position Statements

5.1.5: Licensee Use of Innovative or New Treatment

 **Categories:** 5: Guidance on Procedures and Treatments  Adopted Jan 2020 | Amended May 2021

The Board recognizes that progress in medical science, advances in patient care, and improved outcomes require exploration of innovative treatment and new technology. While the Board supports licensee use of scientifically valid research and innovation, it is the Board's position that licensees must guard against exaggerating or overpromising benefits of participation in research or use of novel or off-label treatment when there is insufficient data to support claims made for the treatment.

The Board acknowledges there are a wide variety of circumstances which may lead a licensee to recommend new or innovative treatment. For example, there may be different considerations when a conventional treatment has failed and a patient wants to individually undertake off-label or novel use of an existing drug or therapy. Licensees must balance respect for patients' autonomy in seeking treatment options against the need to safeguard patients from the risks of novel, but often unproven, treatment.

Licensees offering innovative or novel treatments should:

- Make treatment decisions in the best interest of the patient and use their knowledge and skill for the patient's benefit. Conflicting interests should be resolved to the benefit of the patient.
- Ensure all information, especially in terms of risks, benefits, and efficacy, is presented in an objective and honest manner. Where information is absent or equivocal this should also be communicated to the patient.
- Ensure the patient clearly understands why the new treatment is recommended, its purpose, and how it is different from current or conventional treatment.
- Refrain from using advertising that contains deceptive, false, or misleading claims.
- Avoid promotional "tokens of legitimacy" which might include patient or celebrity endorsements, marketing using various certifications, awards, or citations of licensee affiliation or membership in academic or professional societies connected with the service or product.

- Understand the relevant clinical issues of the treatment offered and have received sufficient education and training from qualified sources regarding the modality to provide treatment in a competent, safe and effective manner.
- Maintain detailed, accurate documentation of the course of treatment and outcomes that includes adverse events, identified both during and after treatment, and which should be communicated to patients in a forthright and timely fashion. New information which may come to light following treatment should also be communicated to the patient.
- Recognize the licensee retains responsibility for patient care and management when using clinical decision-making support tools such as augmented or artificial intelligence.
- Comply with relevant federal, state, and agency laws and regulations.
- Inform patients that innovative or novel treatments may not be covered by certain third-party insurance plans

These guidelines are important in maintaining mutual trust between patient and licensee, protecting patient autonomy, and obtaining meaningful informed consent. The Board's position statement on "[The Licensee-Patient Relationship](#)" may also be helpful to licensees as they consider these issues.

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