Addendum to minutes of February 2025 P&T Committee meeting
November 12, 2026

Spravato was brought back for further consideration. When previously reviewed, the Committee had significant concerns regarding safety and recommended that the product not be covered.

Jesse, Cori and Aimee received a letter from J&J November 11, 2026 requesting that we retract and amend comments made during the February 2025 meeting.

The first point addressed was a comment indicating that "the company was just fined $5 billion for its marketing practices". This statement was inaccurate and will be retracted. For clarification, at the time of the February 2025 meeting, according to Google, J&J had proposed a settlement for talcum powder litigation for $6.5 billion. This was settled in 2026 for $5.5 billion. This was not related to marketing practices. In March 2025, J&J was fined $1.64 billion tied to off-label marketing of its HIV medications. In 2013, J&J was fined $2.2 billion for off-label marketing of Risperdal, Invega and Natrecor. In addition, J&J agreed to pay up to $5 billion in the 2022 National Opioid settlement. It was noted that none of these fines are directly related to Spravato but provided general background to the Committee discussion.

The second item was regarding the statement that "there are several studies comparing Spravato to ketamine and ketamine did better". This statement was accurate and is supported by a systematic review and meta-analysis published in the Journal of Affective Disorders in 2021. This review included 24 studies representing 1877 participants. Racemic ketamine demonstrated greater overall response and remission rates as well as lower dropout rates compared to esketamine. The authors' conclusion was that "intravenous ketamine appears to be more effective than intranasal esketamine for the treatment of depression". (Bahji A, Vazquez G, Zarate C. Comparative efficacy of racemic ketamine and esketamine for depression: A systematic review and meta-analysis. Journal of Affective Disorders. 2021; 278: 542 – 555.) Due to the timing of receipt of the letter in relation to the meeting, additional resources were not sought. Tamara Walker, APRN also noted in her written public comment that in one study comparing the two, ketamine was more effective on secondary outcomes and similar in the primary endpoint when compared to esketamine.

The third item was in relation to the statement that "there are significant safety concerns associated with this medication." This statement will be updated to state "The P&T Committee has significant safety concerns associated with this medication based on the five black box warnings and four additional warnings in the warnings and precautions section of the label."

The final piece was regarding the decision not to cover the medication as it was not considered a "covered outpatient drug". Our interpretation of the law is that it is not a covered outpatient drug as it is always given in a healthcare setting. CFR excludes medications that are bundled into service payments, ie. given as a part of a physician service. J&J's argument is that it is not physician administered because it is self-administered in the physician office. In 2026, CMS established a drug-specific HCPCS code which means that it can be "unbundled". J&J argues that it now must be covered. The P&T Committee has the authority to determine that we cover it. This will be referred to the Attorney General if needed.