



Nab-Paclitaxel

FMEC Responses to Questions From the Drug Programs

Table 1: Response Summary

Drug program implementation questions	Clinical expert response	FMEC response
Considerations for initiation of therapy		
<p>Which patient population is suitable for alternative treatment option with nab-paclitaxel (e.g., previous HSR to paclitaxel and not manageable with premedications)? Please indicate a clear and detailed definition of the patient population.</p>	<p>According to the clinical experts, the term "previous HSR to paclitaxel not manageable with premedication" is accurate and broad enough to allow for clinical judgment. The decision to use nab-paclitaxel should prominently involve clinical judgment. If "clear and detailed" intends to encompass disease site and indication, it would be preferable to conduct a review and compile a list of every disease site for which a combination or single-drug taxane is a preferred regimen (e.g., lung, gynecological, genitourinary, upper gastrointestinal, head and neck).</p>	<p>FMEC agrees with the definition and comments provided by the clinical experts.</p>
<p>Is there a consideration for patients who have contraindications to high doses of steroids?</p>	<p>Per the clinical experts, nab-paclitaxel should be considered for patients with a relative or absolute contraindication to high-dose steroids, which are essential components of premedication for paclitaxel or docetaxel. These instances include, but are not limited to, challenges in managing blood sugar levels in patients living with diabetes and patients who are on immune therapy as part of their chemotherapy regimens.</p>	<p>FMEC agrees with the clinical experts' response.</p>
Considerations for prescribing of therapy		
<p>Given the widespread application of paclitaxel and docetaxel across multiple disease sites and their use in various regimens and/or protocols, is there a necessity for a compilation of "equivalent" nab-paclitaxel dosing and regimens for the more commonly used indications?</p>	<p>The clinical experts agree that there is a need for a compilation of "equivalent" nab-paclitaxel dosing and regimens for the more commonly used indications.</p>	<p>FMEC defers to existing jurisdictional protocols.</p>

FMEC = Formulary Management Expert Committee; HSR = hypersensitivity reaction; nab = nanoparticle albumin-bound.