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Albuterol-Budesonide Rescue for Asthma: MANDALA Safety and Use Patterns

Ryan Quigley:
You're listening to ReachMD, and this is an *AudioAbstract*.

In 2021, about 10 million of the nearly 25 million people living with asthma in the US reported one or more exacerbations. When patients feel symptoms worsening, they often reach for their rescue inhaler. But here's the issue: short-acting beta-two agonist therapy alone doesn't treat the underlying inflammation that's driving those symptoms, and that leaves patients at risk.

I'm Ryan Quigley, and today, I'll be discussing new findings from the MANDALA trial on patterns of use and safety of albuterol-budesonide rescue therapy in adults with moderate-to-severe asthma.

The MANDALA study was the basis for FDA approval of albuterol-budesonide, 180 and 160 micrograms, in 2023 for use as needed in adults with asthma. It showed this combination reduced severe asthma exacerbations by 28 percent and cut systemic corticosteroid exposure by 32 percent compared with albuterol alone. But what did patterns of actual use look like in the trial? And was adding an inhaled corticosteroid to rescue therapy safe when used on top of regular maintenance therapy?

A 2026 original article in *The Annals of Allergy, Asthma, and Immunology* revisited the MANDALA study to determine patterns of use and safety. The phase three, randomized, double-blind trial included adults aged 18 and older with moderate-to-severe asthma. Participants were on ICS-based maintenance therapy and had at least one severe exacerbation in the past year. The safety analysis included 981 patients randomized to as-needed albuterol-budesonide and 981 to as-needed albuterol. Patients documented their rescue medication use each day using an electronic diary over 24 to 52 weeks.

So, let's take a look at the data. Patients in both groups used their rescue medication in similar ways. The mean was 2.6 inhalations per day for albuterol-budesonide and 2.8 for albuterol. That's roughly one to one-and-a-half doses per day. On about one-quarter of days, patients didn't use any rescue therapy at all. And on more than four out of five days, patients used four or fewer inhalations. High daily use—meaning eight or more inhalations in a day—was uncommon. And sustained high use over seven or more consecutive days was rare.

What about adherence to maintenance therapy? Patients reported taking their prescribed maintenance medications on more than 75 percent of days. That meant they were exposed to both maintenance ICS and as-needed ICS from the rescue inhaler.

Let’s look at the safety of this exposure. Adverse event frequencies were nearly identical between groups, at about 47 percent in each arm. Discontinuations due to side effects were one percent or less in both groups. The most common adverse events were nasopharyngitis, headache, COVID-19, and upper respiratory tract infections. Local and systemic ICS-associated adverse events were low and comparable between groups. Oral candidiasis occurred in one percent of patients using albuterol-budesonide versus 0.4 percent with albuterol. Pneumonia was reported in 1.5 percent of the albuterol-budesonide group and 0.6 percent of the albuterol group. But overall, the numbers were small.

The investigators also looked at safety by how much rescue medication patients actually used. Even among the small percentage who used six or more inhalations per day on average, adverse event rates remained comparable between groups.

Of course, there are caveats. This was a clinical trial, so patients were monitored closely and may have behaved differently than they would in everyday practice. Rescue medication use was patient-reported, not electronically captured. And the trial wasn't designed to measure long-term real-world adherence patterns.

But the takeaway is this: in adults with moderate-to-severe asthma on maintenance therapy, adding budesonide to as-needed albuterol

rescue therapy didn't change how often patients used their rescue inhaler. And it was well tolerated, with a safety profile similar to albuterol alone, regardless of how much rescue medication patients used or how much maintenance ICS they were already taking.

This has been an *AudioAbstract*, and I'm Ryan Quigley. To access this and other episodes in our series, visit ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!

Reference:

Chipps BE, Panettieri RA Jr, Skolnik N, et al. Albuterol-budesonide rescue inhaler for asthma: Patterns of use and safety in the MANDALA trial. *Ann Allergy Asthma Immunol.* 2026;136(1):54-60.e3. doi:10.1016/j.anai.2025.07.008