

To Whom It May Concern,

*** is followed in my clinic for asthma. I recently prescribed budesonide-formoterol inhaler therapy, the preferred treatment per asthma guidelines; however, this request was denied.

I am writing to formally request coverage for budesonide-formoterol, which is a combination inhaled corticosteroid (ICS) and rapid-onset long-acting beta-agonist (LABA). This medication is recommended as preferred therapy in 2025 Global Initiative for Asthma (GINA) guidelines, the most widely used international, evidence-based asthma guideline.

Budesonide-formoterol is uniquely supported for use as both:

- Daily maintenance therapy with as-needed reliever therapy (SMART approach)
- As-needed reliever therapy (AIR approach)

It is indicated for children and adolescents with moderate to severe asthma and as an as-needed reliever option even in mild asthma.

Multiple high-quality randomized controlled trials demonstrate that this strategy significantly reduces severe asthma exacerbations, emergency department visits, and hospitalizations compared with traditional regimens:

- **STAY trial** (Chest, 2006)
- **O'Byrne et al.** (AJRCCM, 2005)
- **SYGMA-1 and SYGMA-2** (NEJM, 2018)
- **Beasley et al** (NEJM, 2019)
- **Novel START** (NEJM, 2019)
- **PRACTICAL** (Lancet, 2019)

Use of ICS-formoterol as a maintenance and reliever or reliever only reduced severe exacerbations by **40-60%** when compared with a short-acting beta-agonist.

Importantly, this medication **cannot be substituted** by other ICS-LABA combinations on the formulary. Alternative LABAs such as salmeterol have a delayed onset of action and are **not appropriate or safe for use as rescue therapy**, making them incompatible with guideline-supported SMART/AIR treatment.

For this patient, budesonide-formoterol represents the most evidence-based and guideline-concordant therapy to reduce exacerbation risk, systemic corticosteroid exposure, emergency care utilization, and overall asthma morbidity.

I respectfully request reconsideration and approval for coverage of budesonide-formoterol for this patient.

Please feel free to contact me if additional information is required or if further discussion would be helpful.

Sincerely,

[Name, MD]

[Specialty]

[NPI / Practice]

[Contact Information]