

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]