

# CHEST Medicare Drug Price Negotiation Program Information Collection Request Survey Response

CHEST submitted organizational comments in response to Centers for Medicare and Medicaid Services' (CMS) Information Collection Request regarding drugs primarily utilized in pulmonary, critical care, and sleep medicine that are under analysis within the third cycle of negotiations for the Medicare Drug Price Negotiation Program.

## CMS' Questions Regarding Clinical-focused Experience with Anoro Ellipta:

### Questions: Clinical-Focused Experience

#### *Question 1: Treatment-related Questions*

*What are goals of treatment for the condition(s) treated by Anoro Ellipta?*

- Examples of treatment goals may include but are not limited to disease remission, symptom management, quality of life improvement, or cure.

<b>Response</b>
<p><i>The goals of treatment for Chronic Obstructive Pulmonary Disease (COPD) by Anoro Ellipta include symptom control (i.e. reducing incidents of shortness of breath), disease management (i.e. improving exercise capacity), and reducing exacerbations and hospitalizations.</i></p>

*Question 2: What outcomes do you use to assess improvement or treatment response for this indication(s)?*

- Please provide specific clinical, functional, or patient-reported outcomes.

<b>Response</b>
<p><i>The outcomes used to assess improvement or treatment response are inclusive of clinical, functional, and patient-reported outcomes.</i></p> <p><i>Clinical outcomes often assessed include decreased patient hospitalizations due to COPD and decreased COPD exacerbations.</i></p> <p><i>Functional outcomes often assessed include the Six-Minute Walk Test (6MWT) to measure for functional capacity in COPD or exercise capacity measured in a cardiopulmonary exercise test.</i></p> <p><i>Patient-reported outcomes often assessed include dyspnea Patient-Reported Outcomes (PROs), such as St. George's Respiratory Questionnaire (SGRQ) results, the COPD Assessment Test (CAT), or the Modified Medical Research Council (mMRC) Scale score to assess dyspnea. Additionally, PROs of a decrease in symptoms such as cough and sputum production, and the patient's subjective overall feeling improvement and symptom control are considered in assessment.</i></p>

<b>Response</b>

*Question 3:* What would you consider to be a meaningful improvement or treatment response for the outcomes listed in Question 41b?

<b>Response</b>
<p><i>For patients with COPD, meaningful improvement or treatment response includes improved burden of disease and quality of life measures. Namely, that patients have decreased emergency room visits, the ability to function in daily activities, and exercise.</i></p> <p><i>Additional meaningful improvements include patients have less frequent use of rescue inhalers (i.e., albuterol), less frequency of exacerbation (i.e., reduced prednisone use), as well as measurable improvements in symptom severity assessment scores (i.e. Modified Medical Research Council (mMRC) dyspnea scale and the COPD Assessment Test (CAT)).</i></p>

*Question 4:* Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?

<b>Response</b>
<p><i>How meaningful improvement is measured may differ in subpopulations. The severity of disease, specific phenotypes of disease, as well as comorbidities may impact the goal of therapy and how meaningful improvement is considered. For some patients, the focus may be more preventive (e.g. preventing worsening of condition, preventing exacerbations or hospitalizations) while for others the focus may be more function based (e.g. maintaining the ability to work, perform activities of daily living).</i></p>

### **Question: Additional Treatment-related Questions**

*Question 5:* How does Anoro Ellipta fit into the current treatment paradigm for patients with the condition(s) treated by Anoro Ellipta?

<b>Response</b>
<p><i>Anoro Ellipta is a first-line option in guideline directed therapy for patients with mild to moderate COPD as a combination LABA (long-acting beta-agonist) and LAMA (long-acting muscarinic antagonist). The ability to combine these two classes of medication into a single inhaler reduces inhaler burden to patients, improves adherence and has potential to reduce costs both for payer and for patient.</i></p>

<b>Response</b>

*Question 6* What medications would you consider to be potential therapeutic alternatives for Anoro Ellipta for treatment of the condition(s) treated with Anoro Ellipta? For the list of potential therapeutic alternatives and indications, provide a brief explanation of the reason for the identification of the potential therapeutic alternative(s) of Anoro Ellipta and any indication(s). Reference any citations listed where applicable.

<b>Response</b>
<i>While considerations for therapeutic alternatives depend on a variety of factors including access and cost, alternatives to Anoro Ellipta as a LABA/LAMA include: Stiolto (tiotropium/olodaterol), Bevespi Aerosphere (glycopyrrolate/formoterol), Duaklir (aclidinium bromide/formoterol), and Utibron Neohaler (indacaterol/glycopyrrolate). These classes also exist as separate inhalers which would require 2 medications to replace Anoro—such as Spiriva, Serevent Diskus, Indacaterol, Arformoterol. Additionally, choice of inhaler needs to take into consideration the inspiratory flow necessary to deliver the medication, and patient’s ability to use the inhaler (priming and delivery) which can be impacted by severity of disease process (end stage COPD with lower peak inspiratory flow) or other comorbidities (e.g. arthritis may make some forms harder to use than others).</i>

*Question 7:* What considerations drive treatment selection among Anoro Ellipta and its potential therapeutic alternative(s) for the indication(s)?

- For example, relative efficacy, safety profile, route of administration, patient characteristics, patient preferences, cost, formulary placement, etc.

<b>Response</b>
<i>While considerations for treatment selection depend on a variety of factors including access and cost, examples of additional considerations include efficacy and efficiency, such as patient’s relative lung strength and capacity to generate negative flow and activate a device (i.e. soft mist inhalers may be more suitable for patients with low FEV1s), or the benefits of ease of administration of a single inhaler with dual medications.</i>

*Question 8:* Are there notable differences between how Anoro Ellipta or the potential therapeutic alternative(s) identified in question 6 are prescribed or managed in your practice setting and how these drugs are used in broader clinical practice and/or treatment recommendations in current clinical guidelines for the condition(s) treated with Anoro Ellipta?

- For example, are there general debates or uncertainties related to selection or use of these drugs for the indication(s)?

<b>Response</b>
<i>In general, safety is considered similar within this class of medications and ease of use is a factor of debate across similar devices. Notable differences in prescriptions and treatment recommendations</i>

**Response**

*are also generally impacted by insurance formularies, which often drive the preferred agent for the patient.*

*Question 9: How would you characterize the benefits and risks associated with Anoro Ellipta?*

**Response**

*In general, safety is considered similar within this class of medications.*

*Question 10: What side effects or risks, common or serious, or other safety concerns would you take into consideration when selecting a treatment option from among Anoro Ellipta or its potential therapeutic alternative(s) for the condition(s) treated with Anoro Ellipta?*

**Response**

*Generally, there are no perceived differences in the risk of this class of medications. Patient safety as it relates to a patient's relative lung strength and capacity to generate negative flow and activate a device is taken into consideration. Additionally, symptoms including dry mouth and difficulty urination should be monitored in patients with benign prostatic hyperplasia (BPH).*

*Question 11: In your opinion, how do the benefits and risks associated with Anoro Ellipta differ from the benefits and risks associated with its potential therapeutic alternative(s) for the indication(s)?*

**Response**

*Generally, there are no perceived differences in the risk of this class of medications.*

*Question 12: What specific populations or patient subgroups may derive greater benefits or be at risk for greater harms by using Anoro Ellipta or any of its potential therapeutic alternative(s) for the indication(s)?*

**Response**

*While patients with COPD GOLD Group B and E and above will derive maximum benefits, no significant side effects are observed with these medications in clinical practice. Side effects are mild and typically reversible. No added monitoring is required to routine care of these patients.*

*Question 13: How would you assess whether a patient is tolerating and/or responding to Anoro Ellipta or any of its potential therapeutic alternative(s) when used for each indication(s)?*

- When might you consider discontinuing a medication?
- When might you consider switching to a different medication?
- When might you consider adding another medication to the regimen?

#### **Response**

*Patient response to treatment with Anoro Ellipta is assessed using patient symptoms and/or side effects.*

*Discontinuing a medication may result due to several factors, such as a patient experiencing difficulty in device utilization, a patient experiencing stable symptoms and lung function for a sufficient period of time who may be eligible to step down in treatment, or a change in a patient's ability or inability to afford a medication.*

*Triple therapy may be considered if LABA/LAMA is not effective, particularly in those with high eosinophils counts and with exacerbations. Additionally, if a patient experiences progression of their COPD severity, additional treatments are considered.*

#### **Question: Access and Patient Experience**

*Question 14: What health insurance coverage or access issues do patients experience when trying to obtain Anoro Ellipta and its potential therapeutic alternative(s) for the condition(s) treated by Anoro Ellipta?*

#### **Response**

*The variability and inconsistency in insurance coverage for Anoro Ellipta and its potential therapeutic alternatives drives uncertainty and often results in suboptimal treatment options for patients with COPD. Medication Assistance Programs (MAPs) are present to support some underserved populations but are insufficient to meet the affordability needs of all COPD patients.*

#### **Question: Therapeutic Advance and Unmet Medical Need**

*Question 15: For the condition(s) treated by Anoro Ellipta, describe the extent to which Anoro Ellipta currently represents (or does not represent) a therapeutic advance as compared to its potential therapeutic alternative(s).*

#### **Response**

*Anoro Ellipta currently represents an effective treatment option as a once a day, easy to use combination (LABA/LAMA) inhaler.*

<b>Response</b>

*Question 41c:* Are there widely used evidence-based clinical practice guidelines for the condition(s) treated by the selected drug? If so, please cite these guidelines and explain how they are used to support clinical decision-making. For off-label use, please also reference any citations listed in Question 56 for major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.

<b>Response</b>
<i>Yes, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2026 Report is utilized to provide guidance for when to use each medication (Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease: 2026 Report. Available from: <a href="https://goldcopd.org/2026-gold-report-and-pocket-guide">https://goldcopd.org/2026-gold-report-and-pocket-guide</a>).</i>