Ensifentrine for the Treatment of Chronic Obstructive Pulmonary Disease: Final Policy Recommendations

July 16, 2024

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the June 14, 2024 Midwest CEPAC public meeting on the use of ensifentrine for the treatment of COPD. At the meeting, ICER presented the findings of its revised report on these treatments and the Midwest CEPAC voting council deliberated on key questions related to their comparative clinical effectiveness, potential other benefits and contextual considerations, and long-term value for money at current prices. Following the votes, ICER convened a Policy Roundtable of two patient advocates, two clinical experts, and two payers to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Dr. Steven Pearson, MD, MSc, President of ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

Health Equity

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that effective new treatment options for patients with chronic obstructive pulmonary disease (COPD) are introduced in a way that will help reduce health inequities.

There are important inequities today in the diagnosis and treatment of COPD. Disparities in smoking rates and socioeconomic factors contribute to increased prevalence and worse outcomes of COPD among American Indian/Alaska Native populations,[1] yet their access to diagnosis and treatment lags many other groups.[2] African Americans diagnosed with COPD have a higher risk of exacerbations and worse disease status.[3] Women are more likely to report a delay in diagnosis,[4] in part due to lower smoking rates (three-fourths of never smokers with COPD are women[5]). Finally, people who live in rural communities have greater age-adjusted mortality due to chronic lower respiratory disease, in part due to disparities in access to care.[6]

There is also documented widespread underuse of spirometry for the diagnosis of COPD across all populations.[7] Spirometry is important in achieving accurate diagnoses and in guiding management of COPD, yet data suggest that only around 15% of patients with COPD receive a spirometry test in the year prior to diagnosis, and only about one-third are tested in the year following diagnosis.[8] Numerous reasons have been documented for this underuse, including difficulties accessing lung function laboratories, lack of education about COPD and COPD guidelines, overburdened primary care visits, lack of access to pulmonary specialists, as well as age and comorbidities.[9] Patients who require supplemental oxygen have additional challenges. Due to issues with reimbursement, not all forms of supplemental oxygen are readily available, which may affect mobility and quality of life for people living with COPD.[10] Furthermore, there is low utilization of pulmonary rehabilitation programs, which have been shown to improve COPD disease outcomes,[11] in part due to substantial geographic disparities in access to programs.[12] Thus, reducing inequities in COPD diagnosis and care will require multi-pronged efforts by multiple stakeholders.

To address these concerns:

<u>Manufacturers should take the following actions:</u>

- Include a more diverse patient population in clinical trials, including reflecting the racial and ethnic makeup of the affected population as closely as possible, and including never smokers, who make up an increasing proportion of the COPD population and who are often excluded from COPD clinical trials.

<u>Payers should take the following actions:</u>

- Work with provider groups to improve the basic infrastructure for the diagnosis and management of COPD, including expansion of access and reimbursement for spirometry (e.g., expansion of testing in primary care, pharmacist-led spirometry clinics[13]), and development of telemedicine networks to support primary care-specialist collaboration in the care of patients in areas where specialists are in short supply.

- Ensure that benefit designs developed in conjunction with employers and other plan sponsors do not create requirements for out-of-pocket spending that create major barriers to appropriate access for vulnerable patients.

- As the dominant payer for patients with COPD, Medicare should revise its reimbursement policies for supplemental oxygen. Currently, all forms of oxygen are reimbursed similarly and thus more expensive forms of oxygen, which allow patients with severe and very severe COPD more mobility and a better quality of life, are not easily accessible. To address this concern, Medicare should set differential reimbursement rates such that more expensive forms of oxygen (e.g., liquid oxygen) are accessible to patients who meet guideline-based criteria for use (e.g., patients who are mobile outside the home and who need >3

liters/minute of continuous flow oxygen during exertion[14]). Additionally, guidelines for oxygen coverage should ensure adequate coverage to maximize patients' ability to effectively carry out their daily activities with minimal burdens.

- Medicare also should take steps to improve access to and appropriate use of pulmonary rehabilitation.

Clinical specialty societies should take the following actions:

- Encourage evidence-based, appropriate use of spirometry for the diagnosis and management of COPD by all clinicians caring for people living with COPD. This effort will require educating physicians - particularly primary care physicians – to refer patients for spirometry to confirm diagnosis of COPD, and advocating for increased access and adequate reimbursement for spirometry.

- Clinical specialty societies should continue to use their voice to help advocate for better access to all effective therapies for COPD, including affordable inhalers and access to supplemental oxygen and pulmonary rehabilitation.

Patients and patient advocacy groups should take the following actions:

- Develop and disseminate educational materials to encourage persons with symptoms of COPD to have spirometry testing for an accurate diagnosis.

- Continue to advocate for better access to standard of care therapies (e.g., inhalers, pulmonary rehabilitation), as well as increased access to oxygen and better oxygen systems, as exemplified by the Four Pillars of Oxygen Reform[15] and the Supplemental Oxygen Access Reform Act legislation introduced in the US Congress, and advocated by the COPD Foundation, among others.

- Encourage patients from diverse populations to participate in clinical trials so that clinical trials can accurately reflect the real-world COPD population.

Policymakers/Regulators/Funders should take the following actions:

- State policymakers should extend COVID pandemic-era expansion of telemedicine policies and consider joining interstate compacts that allow for inter-state consultations and broader reimbursement. Many people with COPD will benefit from specialist care, but a shortage of pulmonologists in many areas leads to delays in timely diagnosis and treatment of COPD.

- The FDA and research funders should use all available mechanisms to increase enrollment of underrepresented populations (including never smokers) in clinical trials of COPD

treatments, such that the populations being studied adequately reflect real-world COPD populations.

Payers

Recommendation 1

Payers should include coverage of effective smoking cessation therapies, including nicotine replacement products, pharmacologic therapies, cognitive behavioral therapy (CBT) and combinations thereof, as smoking cessation is a critical part of the treatment of COPD.

Given that many patients with COPD continue to smoke,[16] and that continued smoking is associated with a greater risk of exacerbations[17] and more rapid progression of disease,[18] smoking cessation is a critical part of COPD treatment. Effective smoking cessation interventions include nicotine replacement products, pharmacologist therapies such as buproprion and varenicline, and cognitive behavioral therapy. Because the reasons for continued smoking and the efficacy of interventions vary amongst populations,[19] payers should work to increase access to smoking cessation interventions, including over-the-counter products, to allow for tailoring of treatment to individual patient needs. Furthermore, payers should work with clinicians to promote collecting accurate smoking histories in the medical record to ensure that patients who are smokers can be readily identified and receive appropriate treatment as part of their care for COPD.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy: https://icer.org/wpcontent/uploads/2020/11/Cornerstones-of-Fair-Drug-Coverage-_-September-28-2020.pdf

Drug-Specific Coverage Criteria: Ensifentrine

Although ensifentrine was shown to be effective as add-on therapy for moderate to severe COPD, it was not tested head-to-head against dual LAMA/LABA or triple LAMA/LABA/ICS therapy. Thus, the efficacy of ensifentrine in addition to dual or triple therapy is not known and this will lead payers to develop prior authorization criteria and to consider other limits on utilization, particularly if the launch price is high.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right.[20] To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for ensifentrine.

Coverage Criteria Considerations for Ensifentrine

- **Age:** This treatment will likely be covered for all adult patients with COPD without age thresholds.

- **Clinical eligibility**:

    - **Diagnosis:** Some payers may wish to consider diagnostic spirometry to confirm a diagnosis of COPD, in line with GOLD guidelines and clinical trial eligibility criteria.

    - **Severity:**

        - Although pivotal trial eligibility criteria included that patients should have a score of ≥2 on the mMRC Dyspnea Scale, clinical experts noted that these scales are not necessarily used routinely in clinical practice and did not see a reason to require a measure of severity as a condition of coverage.

        - Clinical experts did not believe it is reasonable for plans to require a specific minimum number of exacerbations per year or other time frame in order to qualify for coverage since documentation of exacerbations may be variable, particularly among patients who have switched insurers within the past year. However, it is expected that payers will require that patients have "exacerbations" while on adequate LAMA/LABA or other standard of care. The definition of exacerbations should be broad, including any hospitalization or emergency department visit or need for a new prescription for oral steroids or antibiotics. Because some exacerbations will not be easily documentable (e.g., patients and clinicians may have pre-set plans for exacerbations including having oral steroids and antibiotics at home for use for exacerbations), payers should consider allowing clinician attestation regarding exacerbation history.

    - **Step Therapy:** The pivotal clinical trial included patients on no maintenance therapy, LAMA or LABA monotherapy, or LAMA or LABA with ICS. However, clinical experts suggested that ensifentrine's role in therapy would be as an add-on to guideline-based dual LAMA/LABA or triple LAMA/LABA/ICS therapy. Therefore, it is not unreasonable for payers to require patients to be on dual LAMA/LABA or triple LAMA/LABA/ICS therapy prior to trying ensifentrine. However, payers should be aware that some patients may not be able to tolerate dual or triple therapy due to side effects or difficulties with inhaler use, and thus there should be a clear and efficient process for requesting exceptions.

    - **Smoking status:** Although the ENHANCE trials were restricted to only smokers with COPD, clinical experts did not believe there was any reason to limit use of ensifentrine to current smokers.

- **Exclusion criteria**: There are no special medical comorbidities at this time that would serve as exclusion criteria for ensifentrine. Clinical experts did not believe that the exclusion criteria from the pivotal trials were appropriate for inclusion in insurance coverage criteria.

- **Dose:** Ensifentrine is delivered by standard jet nebulizer at a dose of 3 mg twice daily.

- **Duration of coverage and renewal criteria**: Initial coverage will likely be for a period of six to 12 months, which is long enough for assessment of efficacy and side effects.

- **Provider restrictions**: Given the importance of optimization of background therapy, clinical experts agreed that it is reasonable to restrict initial prescriptions for ensifentrine to pulmonary specialists or to clinicians in consultation with pulmonary specialists.

Manufacturers

Recommendation 1

Manufacturers should set prices that will foster affordability and access for all patients by aligning prices with the patient-centered therapeutic value of their treatments. For ensifentrine, the manufacturer has priced far above this level and therefore missed an opportunity to provide broad access and increased uptake of the drug.

Drug prices that are set well beyond the cost-effective range cause not only financial toxicity for patients and families using the treatments, but also contribute to general health care cost growth that pushes families out of the insurance pool, and that causes others to ration their own care in ways that can be harmful. For patients with moderate to severe COPD, particularly those with other medical comorbidities, the cost of multiple inhalers can be high and a substantial portion of patients report cost-related non-adherence.[21]

With a new mechanism of action to treat COPD and a favorable side effect profile, there is likely to be significant interest in using ensifentrine for many patients with COPD. Given the large COPD population, the manufacturer of ensifentrine has an important opportunity to support broad access by setting the price in fair alignment with the proven benefits for patients. With current evidence, the ICER report estimated an appropriate health benefit price benchmark to be between $7,500 and $12,700 per year. However, the manufacturer has set an initial launch price of $35,400 per year.[22] At this price, payers are likely to limit access to the drug by administering more stringent prior authorization criteria and/or by placing it on a more expensive pharmacy tier. As a result, it will be more difficult for patients to gain access to an effective drug.

Recommendation 2

The manufacturer of ensifentrine should set up broad distribution networks to limit barriers to access.

The manufacturer should work to ensure a wide distribution network as opposed to limiting access to specific pharmacy networks. Because ensifentrine is a nebulized drug and may be covered under either the medical (durable medical equipment [DME]) or pharmacy benefit, having a wide distribution network (i.e., both pharmacies and DME suppliers) would simplify access for patients and minimize out-of-pocket costs.

Researchers/Regulators

Recommendation 1

Conduct research that directly compares real-world treatment options and sequential treatment effectiveness.

Once FDA approval is obtained, there is often little incentive for manufacturers to pursue head-to-head trials with current standard of care therapies. Appropriate head-to-head trials would inform decision-making by patients and clinicians, particularly as new agents come to market, and there is a role for funders such as NIH and PCORI to encourage and fund such studies. For example, in the case of ensifentrine, the ENHANCE trials were conducted at a time when the standard of care for COPD was different than current guidelines and so it was not tested in patients who were already on dual LAMA/LABA or triple LAMA/LABA/ICS therapy. Despite the lack of evidence, clinical experts indicated that they were most likely to use ensifentrine as add-on therapy to dual or triple therapy. Thus, comparative effectiveness trials are needed to help determine ensifentrine's effectiveness when added on to dual or triple therapy and the subgroups who would benefit most from therapy.

Recommendation 2

Develop new research programs on biomarkers to improve future diagnosis of COPD and to better target treatments to patients who would gain the greatest benefit from new therapies.

The diagnosis of COPD is currently spirometry-based, and as discussed above, there are barriers to accessing spirometry. As a result, some people with symptoms of COPD do not have a formal diagnosis while other people are told they have COPD when they do not actually have the disease.[7] Thus, other methods of diagnosing COPD are needed to both improve diagnostic accuracy and identify potentially untreated COPD patients.[23] For example, computed tomography (CT) scans are now readily available. With the increased use of CT scans for lung cancer screening, for example, developing imaging criteria of COPD could be helpful in securing diagnoses, particularly in more rural areas, where access to spirometry may be difficult.

Additionally, emerging evidence demonstrates that there are likely different subtypes of COPD, even beyond the traditional chronic bronchitis versus emphysema categories.[23] For example, the presence of high levels of eosinophils may represent a more inflammatory type of COPD, which may correspond to a greater response to anti-inflammatory medications such as inhaled corticosteroids. However, more research is needed to define which biomarkers are most useful to define subgroups and tailor treatment. With newer, more expensive treatments for COPD in the pipeline (e.g., ensifentrine, dupilumab), defining treatment subgroups will become increasingly important. Additionally, as biomarkers are validated, the FDA should consider adding guidance to expand the number of biomarkers accepted as trial outcomes and encourage implementation of biomarker outcomes into drug development programs.[23]

Recommendation 3

Expand the set of outcome measures for studies of COPD interventions in order to capture the broader effects of treatment on patients' lives.

The FDA currently focuses on lung function (FEV1), exacerbations, and death for drug approvals. While these are core measures for COPD, they do not fully capture the ways that treatments may help patients. The FDA should seek to include additional outcome measures, including more patient-centered outcome measures, in developmental programs for interventions for people living with COPD.[23]

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Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the June 14, 2024 Public meeting of the Midwest CEPAC.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants*	
Sarah Emond, MPP, President and CEO, ICER	**Grace Ham, MSc**, Program and Events Coordinator, ICER
Grace Lin, MD, Medical Director for Health Technology Assessment, ICER	**Avery McKenna, BS,** Research Lead, ICER
Steve Pearson, MD, MSc, Special Advisor, ICER	**Finn Raymond, BS**, Research Assistant, ICER
David Rind, MD, MSc, Chief Medical Officer, ICER	**Liis Shea, MA**, Senior Program Director, ICER
Mel Whittington, PhD, MS, Senior Fellow Center for the Evaluation of Value and Risk in Health (CEVR), Tufts Medical Center	**Abigail Wright, PhD, MSc**, Research Lead, ICER

*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 2. Midwest CEPAC Panel Member Participants and COI Disclosures

Participating Members of Midwest CEPAC*	
Eric Armbrecht, PhD, Professor, Saint Louis University	**Bijan Borah, PhD**, Professor of Health Services Research, Mayo Clinic College of Medicine and Science
Kurt Vanden Bosch, PharmD, System Formulary Lead, St. Luke's Health System	**Don Casey, MD, MPH, MBA, MACP, FAHA**, Associate Professor of Internal Medicine, Rush Medical College
Yngve Falck-Ytter, MD AGAF, Case Western Reserve University	**Elbert Huang MD**, Professor of Medicine and Public Health Sciences, University of Chicago
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Stuart Winston, DO, Patient Experience Consultant, Trinity-Health IHA Medical Group	

*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Mindy Bauer, PharmD, Pharmacist, IPD Analytics	Mindy Bauer is a full-time employee at IPD Analytics.
Valerie Chang, BA, JD, Executive Director, Hawaii COPD Coalition, Vice Chair of Board, COPD Foundation	Hawaii COPD Coalition receives annual sponsorships from a BCBS insurer and exhibit fees from pharmaceutical companies for the annual COPD Education Day. The COPD Foundation also receives greater than 25% of funding from health care companies.
Stephanie Christenson, MD, MAS, Associate Professor, Division of Pulmonary, Critical Care, Allergy, and Sleep Medicine, UCSF	Dr. Christenson reports grant support from the NIH, American Lung Association, COPD Foundation, and Department of Defense; consulting and advisory board fees from AstraZeneca, Sanofi, Regeneron, GSK, Verona Pharma, Glenmark Pharmaceuticals, Axon Advisors, Apogee Therapeutics, Amgen, Devpro Pharma, Kymera Therapeutics, and Genentech; Non-branded speaking fees from AstraZeneca, GSK, Sanofi, Regeneron, Amgen, Medscape, Horizon CME; writing fees from UpToDate.
Phyliss DiLorenzo, COPD Foundation Board Member	No personal conflicts to disclose. The COPD Foundation receives greater than 25% of funding from health care companies.
David Dohan, MD, Medical Director for Pharmacy and Appeals, Point34Health	Dr. Dohan is a full-time employee at Point34Health.
Juan Rojas, MD, MS, Director of Clinical Informatics & Data Science, Division of Translational & Precision Medicine, and Assistant Professor, Department of Internal Medicine, Division of Pulmonary, Critical Care, & Sleep Medicine, Rush University	No conflicts to disclose.