Understanding Clinical and Economic Impact of Compliance to GOLD Treatment Recommendations in Patients With COPD

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This information is intended only for formulary decision makers or other similar entities making population-based decisions.

COPD, chronic obstructive pulmonary disease; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

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Polling Questions

Please identify your position.

A. Medical director
B. Clinical pharmacist
C. Pharmacy director
D. Other

What is your primary focus?

A. Commercial
B. Medicare Part D
C. Managed Medicaid
D. Other

Polling Questions

Do GOLD recommendations play a role in your formulary decision-making?

A. No, they play no role
B. Yes, they play a minor role
C. Yes, they play a meaningful role

Please select the best description of your understanding of GOLD recommendations and the role they play in COPD.

A. Unaware
B. Minimal
C. Moderate
D. Considerable

Agenda

- GOLD recommendations in COPD
- Study objectives and design
- Results
- Summary

Overview of GOLD Recommendations

GOLD aims to provide clinicians with a nonbiased review for the assessment, diagnosis, and treatment of COPD

- Launched in 1998, in collaboration with the National Heart Lung and Blood Institute, National Institutes of Health, and the World Health Organization, the initial publication was launched in 2001
- Major revisions have occurred in 2006, 2011, and 2017
- These revisions were based on recent information reviewed by the science committee and reflect a comprehensive reassessment of prior recommendations on the diagnosis, assessment, and management of COPD

Global Initiative for Chronic Obstructive Lung Disease. https://goldcopd.org/wp-content/uploads/2019/11/GOLD-2020-REPORT-ver1.0wms.pdf. 2020 Report. Accessed April 9, 2020.

Current GOLD Recommendations

Inhaled Bronchodilators Are the Preferred Maintenance Treatment

- LAMA and LAMA/LABA are the foundational maintenance treatments of COPD for both initial and follow-up pharmacologic treatment
- As with all medical treatments, ICS-containing regimens require assessment of risk vs benefit as regular treatment with ICS increases the risk of pneumonia, especially in patients with severe disease
- Triple therapy is not recommended as initial treatment
- The importance of inhaler selection is recognized
  - Before escalating COPD therapy, switching inhaler and/or molecule should be considered after evaluating a patient's adherence and inhaler technique

ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist; LAMA, long-acting muscarinic antagonist.

Global Initiative for Chronic Obstructive Lung Disease. https://goldcopd.org/wp-content/uploads/2019/11/GOLD-2020-REPORT-ver1.0wms.pdf. 2020 Report. Accessed April 9, 2020.

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Prescribing Behavior Is Not Always Aligned With GOLD

Among patients with COPD, **48%** reported regimens that did not align with 2011 GOLD[a]

29% reported no short-acting or maintenance therapy

45% reported no maintenance therapy

54% of noncompliant treatment was due to underuse

46% of noncompliant treatment was due to overuse

Study Overview

The Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS) is a multicenter cohort study with recruitment from 12 clinical centers and includes former and current smokers (>20 pack-years) with and without COPD and nonsmoking controls. SPIROMICS collected data from 2010 through 2016. The analytical cohort for this study is limited to SPIROMICS participants with spirometry-defined COPD (N=1721). Participants were followed for up to 3 years with annual visits (baseline plus up to 3 annual follow-up visits). Analyses were completed using spirometry from the baseline visit. Medication use was assessed via a questionnaire. Medications were not modified by SPIROMICS investigators.

The most prevalent regimens for patients receiving noncompliant treatment were LABA/ICS for those in 2011 GOLD groups A and B (45% and 23%, respectively) and triple therapy for those in GOLD group C (56%)

[a]The GOLD 2011 report was used in this analysis.

Ghosh S, et al. *Ann Am Thorac Soc*. 2019;16(2):200-208.

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Does compliance with GOLD recommendations impact clinical and economic outcomes?

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Study Objectives Were to Compare

All-cause and COPD-related healthcare resource utilization (HRU)

All-cause and COPD-related healthcare resource costs

COPD exacerbation rates

among patients receiving compliant vs noncompliant treatment according to 2017 GOLD recommendations

Results from real-world studies are not intended for comparisons with clinical trials. Real-world studies were observational trials. Difference in study designs, patient populations, outcomes definitions, and methods of collecting data make it difficult to make comparisons with clinical trials or with each other. Real-world data should be viewed as complementary information.

Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

Methods

A retrospective observational claims study from a large national payor database

- Study period was from January 1, 2013 to March 31, 2018
- Inclusion criteria
  - COPD per a validated claims-based algorithm
  - ≥1 claim for COPD maintenance treatment (index date = earliest fill date)
  - Aged ≥40 years
  - ≥12 months of preindex continuous/concurrent medical and pharmacy coverage (baseline)
  - ≥30 days postindex continuous/concurrent medical and pharmacy coverage (follow up)
- Exclusion criteria
  - Asthma, cystic fibrosis, and/or lung cancer diagnosis
- Multivariate regression analysis was used

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GOLD Compliance Defined

Compliance was based on the ABCD assessment scheme

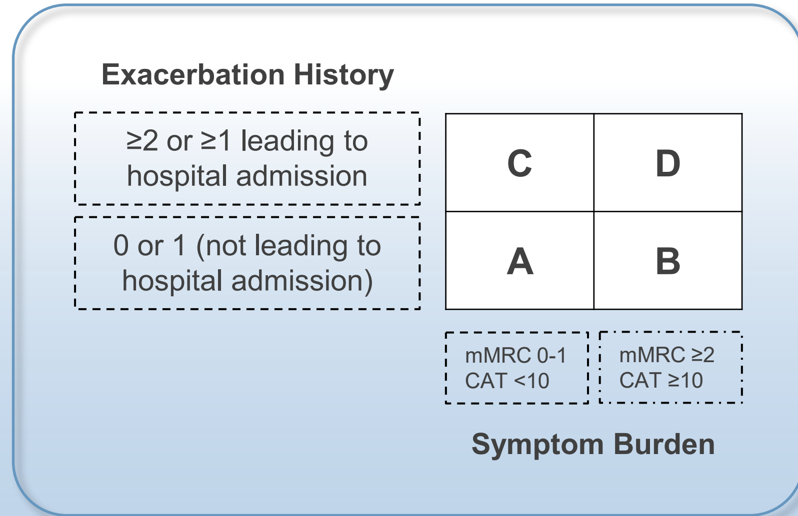
COPD severity grading is based on exacerbation history and symptom burden

GOLD A
- Exacerbations: ≤1 moderate and no severe
- Symptom burden: Low

GOLD B
- Exacerbations: ≤1 moderate and no severe
- Symptom burden: High

GOLD C
- Exacerbations: ≥2 moderate and/or ≥1 severe
- Symptom burden: Low

GOLD D
- Exacerbations: ≥2 moderate and/or ≥1 severe
- Symptom burden: High



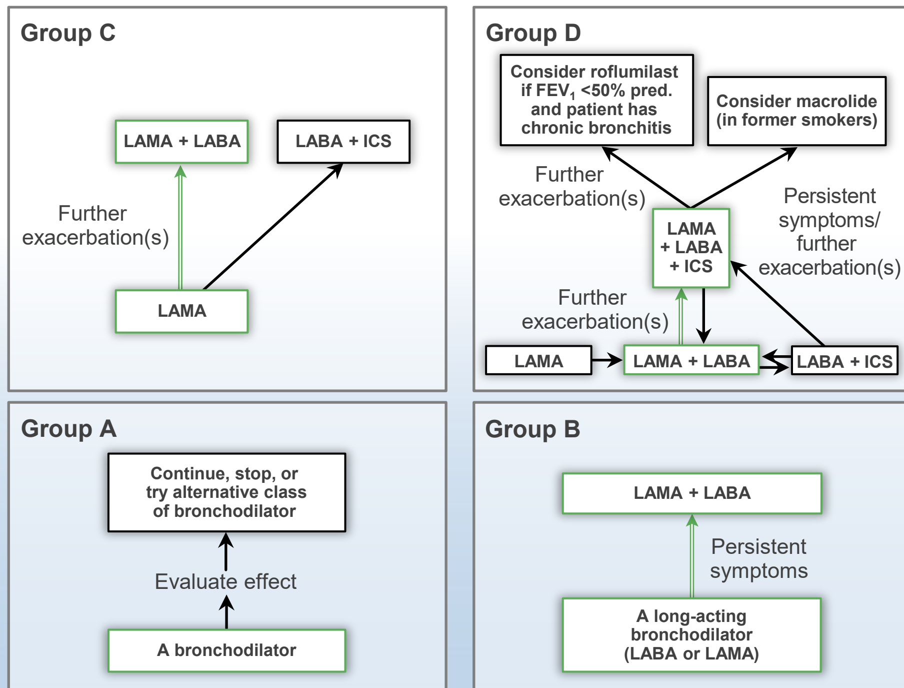
CAT, COPD assessment test; mMRC, Modified British Medical Research Council.

Global Initiative for Chronic Obstructive Lung Disease. https://goldcopd.org/wp-content/uploads/2017/02/wms-GOLD-2017-FINAL.pdf. 2017 Report. Accessed April 9, 2020.

GOLD Treatment Compliance Defined

Pharmacologic Treatment Algorithms[1]

[highlighted boxes and arrows indicate preferred treatment pathways]



Compliance Determination[2]

Group	Treatment History	Compliant Index Treatments
A		SABA, LABA, SAMA, or LAMA
B	If no prior COPD medications	LABA or LAMA
	If with prior use of LABA or LAMA	LAMA+LABA combination
C	If no prior COPD medications	LAMA
	If with prior use of LAMA	LAMA+LABA OR ICS+LABA combinations
D	If no prior COPD medications	LABA+LAMA or LAMA
	If with prior use of LAMA	LAMA+LABA OR ICS+LABA combinations
	If with prior use of LAMA+LABA or ICS+LABA	LAMA+LABA+ICS combinations

In patients with a major discrepancy between the perceived level of symptoms and severity of airflow limitation, further evaluation is warranted.

FEV_1, forced expiratory volume in 1 second; SABA, short-acting beta$_2$-agonist; SAMA, short-acting muscarinic antagonist.

1. Global Initiative for Chronic Obstructive Lung Disease. https://goldcopd.org/wp-content/uploads/2017/02/wms-GOLD-2017-FINAL.pdf. 2017 Report. Accessed April 9, 2020.

2. Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

Outcomes Defined

COPD-related HRU

- Presence of COPD/pneumonia diagnosis or COPD-related treatment (maintenance, rescue, oral corticosteroid, respiratory antibiotics)

COPD-related costs

- Insurer and patient paid (2017 USD)

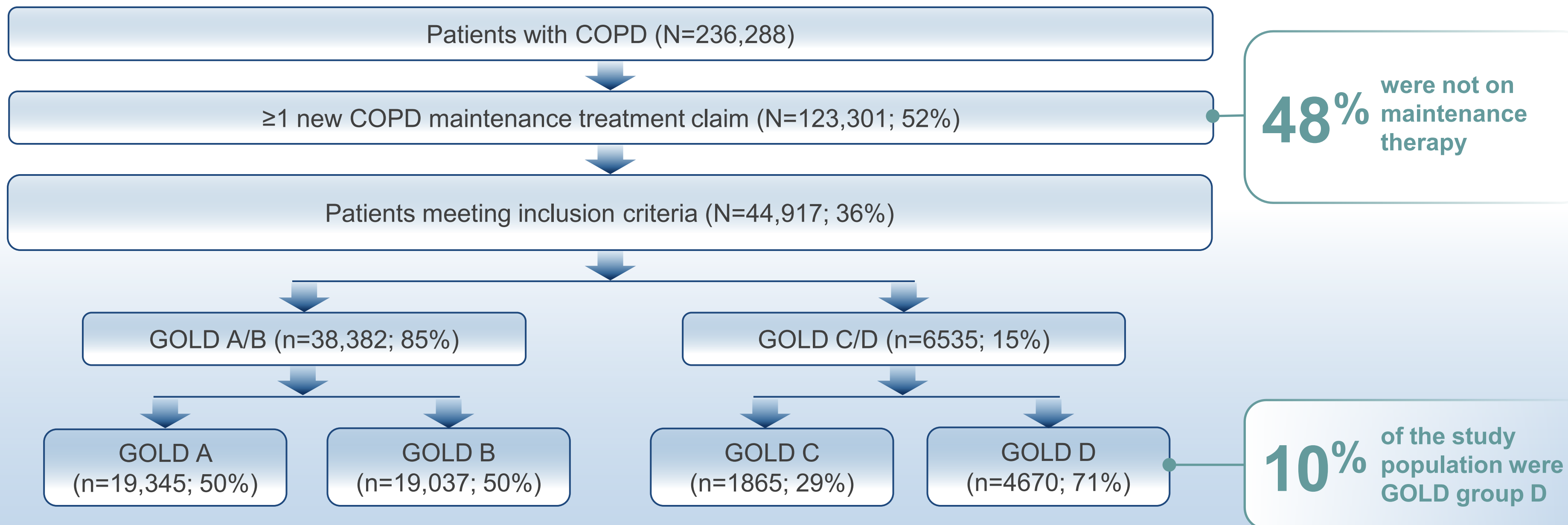
Exacerbations

- Severe exacerbation: An inpatient admission with a COPD diagnosis as primary
- Moderate exacerbation: An emergency department visit with a primary COPD diagnosis or a pharmacy claim for an oral corticosteroid or antibiotic filled within 7 days from the date of an outpatient visit with a COPD diagnosis

USD, US dollars.
Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

Results

Patient Selection



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GOLD Treatment Recommendations Compliance Rates

Patient Population Type	Treatment Recommendation Compliant (%)	Treatment Recommendation Noncompliant (%)
GOLD A/B (n=38,382)	33	67
GOLD C/D (n=6535)	59	41
GOLD A (n=19,345)	34	66
GOLD B (n=19,037)	26	74
GOLD C (n=1865)	34	66
GOLD D (n=4670)	61	39

Among patients noncompliant to GOLD treatment recommendations,

90%

of GOLD A/B patients received ICS-containing regimens

57%

of GOLD C/D received LABA/ICS without prior LAMA-containing therapy

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GOLD-Compliant Treatment Was Associated With Lower COPD-Related HRU

Compliant vs Noncompliant (Mean Difference in Visits per Patient per Year)	**GOLD A/B** (n=38,382)	**GOLD C/D** (n=6535)	**GOLD A** (n=19,345)	**GOLD B** (n=19,037)	**GOLD C** (n=1865)	**GOLD D** (n=4670)
Inpatient	-0.02[a]	-0.12[a]	-0.01	-0.01	-0.07	-0.14[a]
Emergency Department	-0.003	-0.06[a]	-0.004	-0.01	-0.08[a]	-0.06[a]
Office	0.06[a]	-0.28[a]	0.06	0.11[a]	-0.39[a]	-0.16
Outpatient	-0.15	-0.80[a]	0.12	-0.72[a]	-1.31[a]	-1.43[a]

[a]Statistically significant: $P<0.05$.

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GOLD-Compliant Treatment Was Associated With Lower COPD-Related Costs in Groups B, C, and D

Compliant vs noncompliant (Mean Difference in Cost per Patient per Year)	**GOLD A/B** (n=38,382)	**GOLD C/D** (n=6535)	**GOLD A** (n=19,345)	**GOLD B** (n=19,037)	**GOLD C** (n=1865)	**GOLD D** (n=4670)
Medical	-$706[a]	-$2224[a]	$103	-$1534[a]	-$2703[a]	-$2868[a]
Inpatient	-$802[a]	-$2120[a]	-$147	-$1318[a]	-$2014	-$2609
Emergency Department	-$24[a]	-$94[a]	-$10	-$76[a]	-$51	-$127[a]
Office	$14[a]	$42[a]	$13[a]	$1	-$25	$48[a]
Outpatient	$131[a]	$76	$272[a]	-$103	-$473[a]	$23
Pharmacy	$440[a]	$1753[a]	$589[a]	-$335[a]	-$340[a]	$1824[a]
Total	-$265	-$471	$692[a]	-$1869[a]	-$3043[a]	-$1043

[a]Statistically significant: $P<0.05$.
Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

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GOLD-Compliant Treatment Was Associated With a Lower Risk of Exacerbation

Hazard Ratio	Exacerbation	Severe Exacerbation
GOLD A/B (n=38,382)	0.92[a]	0.94
GOLD C/D (n=6535)	0.88[a]	0.81[a]
GOLD A (n=19,345)	0.89[a]	NA
GOLD B (n=19,037)	0.93[a]	NA
GOLD C (n=1865)	0.87[a]	NA
GOLD D (n=4670)	0.90[a]	NA

[a]Statistically significant; *P*<0.05.
Reference category: patients who were noncompliant.
Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

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Limitations

Limitations include those associated with the use of administrative claims data

- The presence of a diagnosis code on a medical claim does not guarantee positive presence of a disease, as the diagnosis code may be incorrectly coded or included as a rule-out criterion
- The presence of a claim for a filled prescription does not indicate that the medication was consumed or that it was taken as prescribed
- The generalizability of the results is limited to similar commercially insured populations and may not be generalizable to government-sponsored health insurance members or those uninsured or underinsured who may not have access to the healthcare resources of interest
- The potential for unmeasured confounding biasing of the results (eg, clinical metrics and lifestyle behaviors that impact disease progression and medication adherence)

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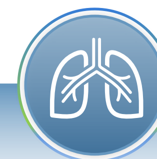
Summary

Summary

GOLD-compliant treatment was associated with

Lower COPD-related HRU

Lower COPD-related costs for GOLD groups B, C, and D



Lower risk of exacerbations

Prescribing compliance to GOLD recommendations continues to be low. The primary driver appears to be the overuse of ICS.

Polling Questions

What information has been surprising to you from the presentation? Choose all that apply.

A. Prescribing is not aligned with GOLD
B. Compliance to GOLD lowers HRU
C. Compliance to GOLD lowers costs
D. Compliance to GOLD lowers the risk of exacerbations
E. None of the above

Of the topics presented, which factors will motivate you to consider GOLD compliance as part of your formulary decision-making? Choose all that apply.

A. ICS use is high and not in accordance with GOLD
B. Compliance to GOLD lowers HRU
C. Compliance to GOLD lowers costs
D. Compliance to GOLD lowers the risk of exacerbations
E. None of the above

Q&A

Q&A

Thank you

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