

## Asthma Relief Inhaler Drug Use Evaluation

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Short acting beta agonist (SABA) inhalers, including albuterol and levalbuterol, have long been a mainstay of treatment for pulmonary conditions including asthma and chronic obstructive pulmonary disease (COPD). In recent years, asthma treatment guidelines have been updated and use of SABA monotherapy or frequent use of SABAs are generally not recommended due to increased risk of adverse events. This newsletter includes data from a drug use evaluation (DUE) of use of SABA inhalers in patients with and without asthma.

### Asthma Guidelines

The 2023 Global Initiative for Asthma (GINA) algorithms provide clinical recommendations for asthma management, and these vary by age range. In recent years recommendations for the use of SABAs have changed in response to evidence of an increased risk for severe exacerbations with SABA monotherapy use in patients with asthma, while use of an inhaled corticosteroid (ICS) significantly reduces that risk.<sup>1</sup> Use of 3 or more SABA inhalers (more than daily average use) in one year is associated with higher risk for severe exacerbations while use of 12 or more inhalers in one year is associated with higher risk of death.<sup>1</sup>

GINA developed tracks for recommendations within certain age groups, with track 1 being preferred and track 2 as an alternative. Each track has steps 1 to 5 for therapy progression from less to more intensive. Agents are categorized as controller or reliever therapy, with ICS-formoterol combination therapy functioning as both controller and reliever. This is called maintenance-and-reliever therapy (MART) or single-inhaler maintenance-and-reliever therapy (SMART). SABA-only treatment is not recommended for asthma in children 6 to 11 years old or adults and adolescents over 12 years old (Table 1).<sup>1</sup>

**Table 1. Initial GINA Therapy Recommendations**

Age	Track	Step 1
5 y and younger	N/A	C: insufficient evidence for daily controller R: prn SABA
6 to 11 y	N/A	C: low-dose ICS when SABA taken R: prn SABA
12 y and older	Track 1	C and R: prn low dose ICS-formoterol
	Track 2	C: ICS taken when SABA taken R: prn SABA or prn ICS-SABA

Abbreviations: C=controller therapy; GINA=Global Initiative for Asthma; ICS=inhaled corticosteroid; N/A = not-applicable; prn=as needed; R=reliever therapy; SABA=short-acting beta agonist; y=years.

## Oregon Health Plan Drug Use Evaluation on Short-Acting Beta Agonist Inhalers

A DUE was conducted to assess how patient utilization mirrored current guideline recommendations for the use of SABA inhalers. It included Oregon Health Plan (OHP) Fee-for-Service (FFS) members without a third-party primary insurance provider who had continuous enrollment between 7/1/2021 and 6/30/2022.<sup>2</sup> Patients identified as having a SABA inhaler claim were assessed for potential indications (e.g., asthma, COPD) documented in medical records at any time in the preceding 6 months, and additional SABA claims in the following 6 months. Claims data was also searched for use of a controller agent 8 weeks before or after the initial SABA fill. There were 1,867 patients who met inclusion criteria; most were over 18 years old, female assigned at birth, and American Indian/Alaskan Native (HNA) (Table 2). The HNA population is highly represented in the FFS compared to the general Medicaid population. Only 459 people (24.6%) had a diagnosis of any type of asthma with 220 (11.8%) categorized as “other or unspecified asthma”.

**Table 2: Demographics Data of FFS members with Short-Acting Beta-Agonist Pharmacy Claims**

	1,867	%
<b>Age groups based on GINA guidelines</b>		
5 years and younger	56	3.0%
6 to 11 years	110	5.9%
12 to 17 years	206	11.0%
18 years and older	1,495	80.1%
<b>Sex</b>		
Female	1,211	64.9%
Male	656	35.1%
<b>Race</b>		
White	436	23.4%
American Indian/Alaskan Native (HNA)	909	48.7%
Hispanic	96	5.1%
Black	23	1.2%
Unknown	398	21.3%
Other	5	0.3%
<b>Asthma</b>	459	24.6%
<b>No Asthma diagnosis</b>	1,408	75.4%
COPD	97	5.2%

Abbreviations: COPD=chronic obstructive pulmonary disease, FFS=fee-for-service, GINA=Global Initiative for Asthma.

In those with an asthma diagnosis, 208 (45.3%) had 3 or more SABA inhalers in 6 months, while 78 (17%) had claims 6 or more in SABA inhalers in 6 months (Table 4). This indicates significant potential overuse for some patients with asthma, though claims level data is unable to differentiate duplicate fills for multiple storage locations.

No claims for concomitant controller medications were identified in 269/459 (58.6%) of patients with asthma and 55/125 (44%) of patients with COPD (n=28 comorbid asthma/COPD), indicating potential SABA monotherapy. The 269 patients includes the young children age group, where SABA monotherapy remains guideline directed (Table 3). Additional details by age group (Table 3) are available based on the total DUE population (n=1867).

**Table 3. Patients with SABA Monotherapy\***

Age	1-2 inhalers/6 mo	>2 inhalers/6 mo
5 y and younger	43	8
6 to 11 y	68	10
12 y and older	885	339

Abbreviations: mo=months; SABA=short-acting beta agonist; y=years.  
\*Not specific to asthma diagnosis, based on total population

In the 1,311 people who did not have a documented diagnosis of asthma or COPD, 349 (26.6%) filled 3 or more SABA inhalers in 6 months. Six or more SABA inhalers in 6 months were filled by 107 (8.2%) of the undiagnosed patients (Table 4). Controller medications were identified in this undiagnosed population in 272 (20.7%) of patients.

**Table 4. Number of SABA Inhalers by Member**

# Inhalers*	Asthma Diagnosis N=459†	COPD Diagnosis N=125†	Neither Diagnosis N=1311
1	164 (35.7%)	27 (21.6%)	689 (52.6%)
2	87 (19.0%)	18 (14.4%)	273 (20.8%)
3	63 (13.7%)	15 (12.0%)	125 (9.5%)
4	40 (8.7%)	14 (11.2%)	73 (5.6%)
5	27 (5.9%)	9 (7.2%)	44 (3.4%)
6	31 (6.8%)	12 (9.6%)	40 (3.1%)
>6	47 (10.2%)	30 (24.0%)	67 (5.1%)

Abbreviations: COPD=chronic obstructive pulmonary disease; SABA=short-acting beta agonist.  
\*In 6 months; † N=28 comorbid asthma/COPD

This analysis is subject to the limitations of claims data, which may not accurately reflect true medication use (e.g., duplicate claims with intent to store in multiple locations such as home and school, lost inhalers), and a short time window with enrollment requirements which limited the subject populations. However, the results do indicate that SABA monotherapy in patients older than 5 years is present in a notable proportion of patients with asthma. Potential SABA overuse, indicated by fill

quantities above thresholds quoted by GINA was identified. Use of controller medications and multiple SABA fills in patients who are not diagnosed with asthma or COPD is also of concern.

**Policy Update**

Full results from this DUE were presented to the FFS Pharmacy and Therapeutics committee in October 2023. Several recommendations were made at that meeting including a one-time provider fax requesting SABA therapy assessment for:

- Patients without asthma or COPD and more than 2 SABA inhalers in 6 months.
- Patients with asthma who are 6 years or older identified as having SABA monotherapy.
- Patients with mild persistent asthma, moderate persistent asthma, or severe persistent asthma with any SABA claim regardless of concomitant controller therapy.
- Patients with asthma and claims for 2 or more SABA inhalers in 6 months regardless of concomitant controller therapy.

These fax notifications are informational, as claims and diagnostic records have inherent limitations.

Additionally, it was recommended to begin ongoing informational provider notification when 3 SABA inhalers are filled within 6 months (excluding COPD diagnosis) and to investigate creating a soft-stop pharmacy point-of-sale educational messaging for the pharmacist to counsel/assess the patient and follow-up with a provider as needed when 6 SABA claims are identified in 6 months.

**Key Points**

- Short-acting beta agonist (SABA) inhaler overuse and monotherapy increase risk of morbidity and mortality.
- Monotherapy use of SABA inhalers was seen in 58.6% of OHP patients with asthma.
- Potential SABA overuse was seen in 45.3% of patients with asthma and 26.6% of patients filling SABA inhalers without a diagnosis of COPD or asthma.
- Several provider notification initiatives will be implemented to promote reassessment of SABA therapy in identified at-risk populations.
- The full DUE report is available at: [www.orpd.org/durm/meetings/meetingdocs/2023\\_10\\_05/archives/2023\\_10\\_05\\_Asthma\\_rescue\\_inhalers\\_DUE.pdf](http://www.orpd.org/durm/meetings/meetingdocs/2023_10_05/archives/2023_10_05_Asthma_rescue_inhalers_DUE.pdf)

## Conclusion

Monotherapy use of SABA inhalers in patients with asthma, and potential SABA overuse in patients with asthma, COPD, and patients who have no formal diagnosis of asthma or COPD were identified in a concerning proportion of patients. There is the potential for increased risk of exacerbations and death in these patients.

*Peer Reviewed By: Jennifer J Stanislaw, PharmD, BCACP, Oregon State College of Pharmacy and Tracy Klein, PhD, ARNP, FAANP, FRE, FAAN, Associate Professor, College of Nursing Washington State University Vancouver*

## References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated May 2023. Available from: [www.ginasthma.org](http://www.ginasthma.org). Accessed June 8, 2023.
2. Drug Use Evaluation: Asthma Rescue Inhalers. Drug Use Research and Management. Oregon State University. Available at: [www.orpdl.org/durm/meetings/meetingdocs/2023\\_10\\_05/archives/2023\\_10\\_05\\_Asthma\\_rescue\\_inhalers\\_DUE.pdf](http://www.orpdl.org/durm/meetings/meetingdocs/2023_10_05/archives/2023_10_05_Asthma_rescue_inhalers_DUE.pdf)