



Drug Use Evaluation: Asthma Rescue Inhalers

Plain Language Summary:

- Clinical practice guidelines for the treatment of asthma have changed in the past few years. Inhaled medicines called short-acting beta agonists (SABA) alone are no longer recommended for most patients with asthma, and may actually make asthma control worse when used without other asthma medicines. An example of a short-acting beta agonist is albuterol.
- The purpose of this evaluation is to assess if short-acting beta agonist use has changed to match recommendations in the current clinical guidelines, and if overall use of short-acting beta agonist inhalers is appropriate in fee-for-service/open card Medicaid members.
- We found that many patients with asthma who are using short-acting beta agonists are not receiving additional medications for asthma. Most patients should be taking a medicine called an inhaled corticosteroid, such as budesonide. An inhaled corticosteroid paired with a different beta agonist (formoterol) decreases severe asthma attacks compared to only using short-acting beta agonist inhalers. Many patients have filled prescriptions for so many short-acting beta agonist inhalers that they may be at higher risk of bad health outcomes. These include hospitalization and death. Most of the patients who received a short-acting beta agonist inhalers did not have asthma or chronic obstructive pulmonary disease (COPD) in medical records. It is unclear if this is due to inaccurate medical records or other medical uses of this type of medicine.
- DURM recommends putting in place a quantity limit for short-acting beta agonist inhalers to prevent potentially harmful overuse in patients.
- DURM recommends notifying medical prescribers of asthma patients who appear to be receiving short-acting beta agonist inhalers when other therapy might be more beneficial. Other types of inhalers, which match current guideline recommendations are available to fee-for-service/open card Medicaid members.

Research Questions:

- What proportion of Fee-For-Service (FFS) members with claims for a SABA rescue inhaler also have claims for controller inhaler therapy?
- How many FFS members have multiple claims for SABA inhalers indicating potential overuse (overuse is defined as daily use of ≥3 canisters [200 count] in a year with extremely high use as 12 or more canisters in a year)?
- Do FFS members with SABA claims, indicating overuse or monotherapy, have more adverse outcomes (e.g., hospitalizations, emergency department visits, or asthma exacerbations) than those using SABA with controller medications and without excessive use of a controller?
- Are there subgroups of FFS members based on demographics (e.g., age, diagnoses, or symptom severity) who are more likely to overuse SABA in their asthma treatment regimen?

Conclusions:

- There were 459 patients with an asthma diagnosis identified as having a SABA claim. Controller therapy of some kind was identified in 41.4% (N=190) of those patients (**Table 3**).
- Potential SABA overuse was identified in 208 (45%) of the 459 patients with diagnosed asthma. Extremely high use was identified in 78 patients (17%) carrying an asthma diagnosis (Table 2).
- Oral corticosteroid use appeared highest for members with claims for more than 5 inhalers (28.7%; N=62). The rate of emergency room visits was also highest in those with more than 5 inhalers compared to the other subgroups (Table 5). Hospitalization rates were similar among subgroups, while deaths were almost twice as common in members receiving 2 to 5 inhalers (2.2%, N=17) or more than 5 inhalers (2.3%; N=5) compared to all members with SABA prescriptions (1.5%; N=28) and SABA monotherapy (1.2%; N=16). Given high rate of non-asthma diagnoses and differences in number of inhalers seen in subgroups with and without asthma or COPD, the outcome groups compared in Table 5 are likely fundamentally different patient populations.
- The most common asthma subtype in patients with SABA claims was "unknown or unspecified" (47.9%, 220 of 459). Most patients identified were female assigned at birth (64.9%) and of Native American or Alaskan native (HNA) ancestry (48.7%). The HNA population is highly represented in fee-for-service/open card Medicaid compared to the general Medicaid population.
- Patients with neither a diagnosis of asthma or COPD represented most of the population identified as having a SABA claim (70.2%, 1311 of 1867). These patients were most likely to only have claims for 1 (52.6%, N=689) or 2 (20.8%, N=273) inhalers in the 6 month follow up period (Table 2 and 6), though 242 patients (18.5%) had claims for 3-5 inhalers and 107 patients (8.2%) had claims for 6 or more inhalers. A post-hoc analysis revealed many of these patients had cough (13.6%, N=178), nicotine dependence (12.7%, N=167), and abnormalities of breathing (11.6%, N=152). They likely received SABA for acute infections such as upper respiratory tract infections, viral illnesses, acute pharyngitis (Table 6).

Recommendations:

- Implement one-time targeted provider fax notification requesting SABA therapy reassessment for specific patients identified in this DUE:
 - All patients without either asthma or COPD diagnosis with more than 2 SABA inhalers in 6 months.
 - o All patients with asthma who are 6 years or older identified as having SABA monotherapy.
 - All patients with mild persistent asthma, moderate persistent asthma, or severe persistent asthma with any SABA claim regardless of concomitant controller therapy.
 - All patients with asthma and claims for 2 or more SABA inhalers in 6 months regardless of concomitant controller therapy.
- Implement targeted ongoing RetroDUR with provider fax notification when 3 SABA inhalers are filled within 6 months. Exclude patients with COPD diagnosis.
- The committee considered and rejected implementation of a quantity limit for more than 6 SABA claims in 6 months with exclusion of patients with a COPD diagnosis. The committee asked staff to investigate the possibility of point-of-sale educational messaging that will not stop a prescription fill.

Background

Asthma is a heterogenous, non-communicable disease, typically characterized by chronic airway inflammation. Typical respiratory symptoms include wheezing, shortness of breath, chest tightness, and cough.¹ Patients with this disease exhibit variable expiratory airflow limitation, which may become persistent.² Asthma severity varies is typically treated with inhaled beta-agonists and different strengths of inhaled corticosteroids (ICS).¹ Other therapies for asthma include oral leukotriene receptor antagonists (LTRA), inhaled muscarinic agents, and injectable biologic agents, which are reserved for patients with more severe and difficult to control asthma.¹ Oral corticosteroids are used in exacerbations and can be considered in those presenting with severe uncontrolled asthma.¹ Treatment

regimens involve "reliever" therapy for immediate symptoms and "controller" therapy to prevent exacerbations and control symptoms.¹ Treatments progress along a stepwise algorithm based on frequency and severity of symptoms.¹ The Global Initiative for Asthma (GINA) algorithms differ slightly between age groups.¹

In 2019, GINA changed recommendations regarding use of inhaled SABA as evidence shows that patients treated with SABA-monotherapy had an increased risk of severe exacerbations and that ICS significantly reduces the risk.^{2,3} Higher use of SABA (ie., Daily use or \geq 3 canisters [200 count] in a year) is associated with higher risk for severe exacerbations while 12 or more canisters in a year is associated with much higher risk of death).¹ Guidelines for COPD differ.⁴

Step 1 treatment for adults and adolescents (12 years and older) recommend ICS containing controller treatment. These recommendations were clarified in 2021.^{1,2} Current recommendations are for Track 1 (preferred) use of ICS-formoterol as the reliever medication.¹ Formoterol is a long-acting beta agonist (LABA) with rapid onset. Track 2 (alternative) recommendations include a SABA reliever with use of an ICS anytime SABA is taken either as a combination inhaler or separate inhalers (Step 1) or low dose maintenance ICS (Step 2).¹

Treatment recommendations for children (6 to 11 years) differs as there is one track and Step 1 includes low-dose ICS as a controller, taken when SABA reliever is taken, with an alternative for daily lose dose ICS. Step 2 involves daily low dose ICS as the controller, though a low dose ICS taken when SABA reliever taken or a daily LTRA are alternatives as controllers. Children 5 years and younger in Step 1 are the only age group where SABA reliever without a separate controller are recommended. Daily ICS (preferred) or daily LTRA (alternative) or short courses of ICS (alternative) are the controller therapies for Step 2 in this age group.

Based on this guidance, SABA use without ICS is only preferred in ages 5 years and younger in Step 1.¹ Certain patients 5 years and younger and 6 to 11 years in Step 2 using daily LTRA as an alternative controller therapy may have SABA reliever use without ICS.¹ Those patients aged 12 years and older should preferentially receive ICS-formoterol rather than a SABA with separate ICS or SABA-ICS combination product, but all patients in this age range should have some form of ICS controller in these steps.¹

Inhalers with SABA, ICS, LABA and their combinations are categorized in several different preferred drug list (PDL) classes. The LABA and ICS single agent classes have a prior authorization (PA) for non-preferred agents to ensure appropriate combination use with other single-agent inhalers. Combination LAMA-ICS. Inhalers only have preferred and non-preferred status. There are preferred options of SABA (albuterol) in inhaler and nebulizer form, salmeterol xinafoate (SEREVENT DISKUS), and multiple single agent ICS. Multiple LABA-ICS combinations are preferred, including two different ICS-formoterol options. Gross costs for SABA and ICS classes were approximately \$110,000 in the first quarter of 2023. Combination LABA-ICS costs were \$200,000 during the same time period while single agent LABA use was minimal compared to the other two. Drugs in these classes can additionally be used in patients with COPD.

Methods:

Oregon Health Plan (OHP) members were identified for inclusion based on paid FFS claims for a SABA inhaler (**Appendix 2, Table C, Inhaler formulations**). The evaluation window for SABA was from 7/1/21 to 6/30/22. The index event (IE) was defined as the first paid FFS claim for a SABA in the evaluation window. Demographics were evaluated at the time of the IE.

The following timeframes were used to evaluate outcomes and determine inclusion of members in the study:

- Baseline period: 6 months before the IE (exclusive of the IE)
- Follow-up period: 6 months after the IE (inclusive of the IE)

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Members were categorized into groups by:

- Diagnoses present in medical claims in the 6 month baseline period. Diagnoses of interest included asthma and COPD (defined in Appendix 2, Table J).
- Presence or absence of an asthma controller medication in the 8 weeks before or after the IE. Asthma controller therapy is defined based on drugs in Appendix 2 (Tables B, D, E, F, G, and I).

Inclusion Criteria:

1. At least one point-of-sale (POS) FFS paid claim for SABA inhaler during the evaluation window

Exclusion Criteria:

1. Individuals with benefit packages listed below. Certain benefit packages have limited or no drug benefits, and claims may be incomplete.

Category	Benefit Package	Description
Medicare Part D coverage	вмм	Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug
	BMD	Oregon Health Plan with Limited Drug
	MED	Qualified Medicare Beneficiary
Limited or no Medicaid	MND	Transplant package
drug benefit	CWM	Citizenship Waived Emergency Medical
	SMF	Special Low-Income Medicare Beneficiary Only
	SMB	Special Low-Income Medicare Beneficiary Only

- 2. Non-continuous Medicaid eligibility during the baseline period
- 3. Non-continuous FFS eligibility during the follow-up period
- 4. Members with third-party liability during the baseline or follow-up period

Outcomes evaluated in this analysis included:

- Emergency department visit, hospitalization, or prescription for oral corticosteroid in the follow-up period (6 months). Codes for oral corticosteroids are defined in **Appendix 2, table H**.
- Number of SABA inhalers dispensed in the 6 month follow-up period, where inhalers are defined based on package size for a given NDC. Each HFA inhaler contains 200 doses. According to GINA 2023 SABA use of 3 or more 200 dose canisters in a year, corresponding to average use more than daily (1.6 doses/day) and increases risk of asthma exacerbations, and 12 or more canisters in a year increases risk of death. Since this study evaluated a shorter follow up period, we defined overuse as more than 2 inhalers over 6 months.
- Proportion of members with prescribed asthma controller therapy in the 8 weeks before or after the IE (inclusive of the IE). The total 16 week period was chosen to identify and include any members who were filling maintenance controller medication for a 90 day supply.
- Subgroups based on diagnoses or asthma severity were analyzed to determine if these outcomes varied by group. For patients with medical claims denoting more than one different asthma severities, members were categorized based on the more severe diagnosis and most specific diagnosis. For example, members with diagnoses of both mild intermittent and mild persistent asthma would be categorized as mild persistent. Members with diagnoses of both moderate persistent and other/unspecified asthma would be categorized as moderate persistent.
- Post-hoc assessment of most common medical diagnoses likely associated with SABA claim.

Results:

Table 1 describes characteristics for patients prescribed SABA inhalers. Most patients were adult females assigned at birth of American Indian/Alaskan Native descent. Nearly 20% were children, and 3% were 5 years of age or younger. Asthma diagnosis was recorded in 24.6% of patients, while 75.4% of patients had no recorded diagnosis of asthma and only 5.2% of that group carried a COPD diagnosis.

Table 1: Demographics Data of FFS members with Short-Acting Beta-Agonist Pharmacy Claims

	1,867	%
Age groups based on GINA guidelines	50	0.00/
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%
Sex		
Female	1,211	64.9%
Male	656	35.1%
Race		
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%
Asthma Type		
Asthma	459	24.6%
Mild intermittent asthma	94	5.0%
Mild persistent asthma	41	2.2%
Moderate persistent asthma	87	4.7%
Severe persistent asthma	17	0.9%
Other and unspecified asthma	220	11.8%
No Asthma diagnosis	1,408	75.4%
COPD	97	5.2%

A total of 1,867 patients had at least 1 SABA claim in the follow-up period, 459 of these had a diagnosis of asthma and 125 a diagnosis of COPD (N=28 both asthma+COPD). Nearly half of patients with a SABA claim received only a single inhaler claim during the six month follow-up period. This varied by diagnosis and those with COPD were the most likely subgroup to fill claims for four or more inhalers and 24% received more than six SABA inhalers. Over half of patients with asthma filled 2 or more SABA inhalers in the 6 month time period, indicating possible daily use, while 17.0% (N=78) of patients with asthma filled 6 or more SABA inhalers in 6 months. Patients with neither asthma or COPD were most likely to only have a single SABA inhaler claim.

	All membe SABA o	All members with a SABA claim		Asthma Diagnosis		COPD Diagnosis		agnosis
	1,867	%	459	%	125	%	1,311	%
Number of inhalers								
1	877	47.0%	164	35.7%	27	21.6%	689	52.6%
2	373	20.0%	87	19.0%	18	14.4%	273	20.8%
3	200	10.7%	63	13.7%	15	12.0%	125	9.5%
4	124	6.6%	40	8.7%	14	11.2%	73	5.6%
5	77	4.1%	27	5.9%	9	7.2%	44	3.4%
6	79	4.2%	31	6.8%	12	9.6%	40	3.1%
>6	137	7.3%	47	10.2%	30	24.0%	67	5.1%

Table 2: Number of SABA inhalers filled by individual members in a 6 month follow-up period

Table 3 describes patients with SABA claims by diagnosis and concomitant medication therapy. SABA monotherapy was identified in 58.6% (N=269) of patients with asthma, 44% of patients with COPD (N=55), and 79.3% (N=1039) of patients without asthma or COPD.

Table 3: Concomitant Controller Drugs by Indication

	All members with a SABA claim		Asthma Diagnosis		na COPD osis Diagnosis		Neither Diagnosis	
	1,867	%	459	%	125	%	1,311	%
	-		_	-		-	-	-
SABA only (monotherapy)	1,353	72.5%	269	58.6%	55	44.0%	1,039	79.3%
SABA + controller	514	27.5%	190	41.4%	70	56.0%	272	20.7%
SABA + Leukotriene only	56	3.0%	18	3.9%	3	2.4%	36	2.7%
SABA + ICS/ICS combo product +/- additional controllers	452	24.2%	169	36.8%	63	50.4%	236	18.0%
SABA + anything else	110	5.9%	49	10.7%	22	17.6%	48	3.7%

Pediatric and adolescent patients with SABA claims were more likely to only have 1-2 inhalers in 6 months compared to more than 2 inhalers. Adults made up the vast majority of patients with more than 2 inhaler claims (88.7%; N=547) compared to younger ages, and patients with comorbid COPD were also more likely to have more than 2 inhalers (13.0%; N=80) compared to 1-2 inhalers (3.6%; N=45). Those with an asthma diagnosis were most commonly classified as "other or unspecified asthma" (N=220) compared to other specific asthma severities. Most patients with severe persistent and moderate persistent asthma were more likely to have more than 2 inhaler claims compared to 1-2 inhaler claims (2.6%, N=16 vs. 0.1%, N=1 for severe; 8.8%, N=54 vs. 2.6%, N=33 for moderate). There were 51 children 5 years and younger with SABA monotherapy, and 8 of those children had greater than 2 inhalers. Similarly, 78 children 6 to 11 years had SABA monotherapy and 10 of those children received greater than 2 inhalers. Most people with SABA monotherapy were 12 years or older and 339 of them received more than 2 inhalers in the 6 month follow up period.

Table 4: Short-Acting Beta-Agonist Overuse by Subgroup

	Patients by count of SABA Inhalers in 6 month follow-up period						
	1-2 Inha	alers	>2 Inhalers				
	1,250	%	617	%			
Age groups based on GINA guidelines							
5 years and younger	47	3.8%	9	1.5%			
6 to 11 years	91	7.3%	19	3.1%			
12 to 17 years	164	13.1%	42	6.8%			
18 years and older	948	75.8%	547	88.7%			
Asthma Severity							
Mild intermittent asthma	61	4.9%	33	5.3%			
Mild persistent asthma	22	1.8%	19	3.1%			
Moderate persistent asthma	33	2.6%	54	8.8%			
Severe persistent asthma	1	0.1%	16	2.6%			
Other and unspecified asthma	134	10.7%	86	13.9%			
Comorbid COPD	45	3.6%	80	13.0%			
SABA Monotherapy							
5 years and younger	43	3.4%	8	1.3%			
6 to 11 years	68	5.4%	10	1.6%			
12 years and older	885	70.8%	339	54.9%			

Oral corticosteroid use appeared highest for members with claims for 2 to 5 inhalers (19.3%; N=149) and more than 5 inhalers (28.7%; N=62). The rate of emergency room visits was also highest in those with more than 5 inhalers compared to the other subgroups **(Table 5)**. Hospitalization rates were similar among subgroups, while deaths were almost twice as common in members receiving 2 to 5 inhalers (2.2%, N=17) or more than 5 inhalers (2.3%; N=5) compared to all members with SABA prescriptions (1.5%; N=28) and SABA monotherapy (1.2%; N=16).

Table 5: Short-Acting Beta-Agonist Overuse and Adverse Events in the follow-up period

	ALL members with	ALL members with SABA Rx		LL members with SABA Rx Members with SABA monotherapy			Members w claims indic inhalers in	rith SABA cating 2-5 6 months	Members with SABA claims indicating >5 inhalers in 6 months	
	1,867	%	1,353	%	774	%	216	%		
Members with claims for oral corticosteroids	343	18.4%	221	16.3%	149	19.3%	62	28.7%		
Members with emergency room visits	604	32.4%	439	32.4%	257	33.2%	82	38.0%		
Members with hospitalizations	115	6.2%	79	5.8%	54	7.0%	15	6.9%		
Death	28	1.5%	16	1.2%	17	2.2%	5	2.3%		

Table 6 represents a post-hoc analysis of the 1311 (70.2%) patients with SABA claims but without a diagnosis of asthma or COPD. Patients may have more than one or zero of the ICD 10 codes of interest. These patients were most likely to only have claims for 1 (52.6%, N=689) or 2 (20.8%, N=273) inhalers in the 6 month follow up period, though 242 patients (18.5%) had claims for 3-5 inhalers and 107 patients (8.2%) had claims for 6 or more inhalers. Cough (13.6%, N=178), nicotine dependence (12.7%, N=167), and abnormalities of breathing (11.6%, N=152) were these most common diagnoses listed in these patients. Various types of acute respiratory infections such as upper respiratory tract infections, acute pharyngitis, and viral illnesses were identified in this list.

rouped	by first 3 digits of ICD-10 code										
				Memb	pers with N	leither As	thma or CO	OPD Diag	gnosis		
		Any nu Inha	mber of alers	1 Inh	aler	2 Inf	nalers	3-5 Ir	halers	>=6 lı	nhalers
ICD	Description	1,311	%	689	%	273	%	242	%	107	%
R05	Cough	178	13.6%	109	15.8%	41	15.0%	21	8.7%	7	6.5%
F17	Nicotine dependence	167	12.7%	93	13.5%	24	8.8%	37	15.3%	13	12.1%
R06	Abnormalities of breathing	152	11.6%	85	12.3%	27	9.9%	29	12.0%	11	10.3%
U07	Emergency use of U07	108	8.2%	64	9.3%	19	7.0%	17	7.0%	8	7.5%
J06	Acute upper resp infections of multiple and unsp sites	90	6.9%	57	8.3%	16	5.9%	16	6.6%	1	0.9%
J02	Acute pharyngitis	85	6.5%	53	7.7%	18	6.6%	11	4.5%	3	2.8%
R53	Malaise and fatigue	83	6.3%	47	6.8%	15	5.5%	17	7.0%	4	3.7%
G47	Sleep disorders	75	5.7%	34	4.9%	11	4.0%	23	9.5%	7	6.5%
R09	Oth symptoms and signs involving the circ and resp sys	75	5.7%	47	6.8%	14	5.1%	13	5.4%	1	0.9%
J30	Vasomotor and allergic rhinitis	49	3.7%	24	3.5%	10	3.7%	11	4.5%	4	3.7%
Z72	Problems related to lifestyle	43	3.3%	21	3.0%	4	1.5%	13	5.4%	5	4.7%
J01	Acute sinusitis	36	2.7%	18	2.6%	6	2.2%	11	4.5%	1	0.9%
R91	Abnormal findings on diagnostic imaging of lung	36	2.7%	20	2.9%	5	1.8%	5	2.1%	6	5.6%
J98	Other respiratory disorders	28	2.1%	12	1.7%	6	2.2%	6	2.5%	4	3.7%
J03	Acute tonsillitis	26	2.0%	17	2.5%	5	1.8%	3	1.2%	1	0.9%
B34	Viral infection of unspecified site	25	1.9%	17	2.5%	7	2.6%	1	0.4%	0	0.0%
J18	Pneumonia, unspecified organism	22	1.7%	13	1.9%	3	1.1%	6	2.5%	0	0.0%
Z86	Personal history of certain other diseases	20	1.5%	9	1.3%	6	2.2%	5	2.1%	0	0.0%
J96	Respiratory failure, not elsewhere classified	19	1.4%	9	1.3%	1	0.4%	7	2.9%	2	1.9%
J34	Other and unspecified disorders of nose and nasal sinuses	15	1.1%	9	1.3%	2	0.7%	3	1.2%	1	0.9%
J12	Viral pneumonia, not elsewhere classified	14	1.1%	10	1.5%		0.0%	2	0.8%	2	1.9%
J32	Chronic sinusitis	14	1.1%	9	1.3%	2	0.7%	1	0.4%	2	1.9%
J20	Acute bronchitis	13	1.0%	5	0.7%	3	1.1%	4	1.7%	1	0.9%
J40	Bronchitis, not specified as acute or chronic	9	0.7%	5	0.7%	2	0.7%	1	0.4%	1	0.9%
J43	Emphysema	8	0.6%	4	0.6%	1	0.4%	2	0.8%	1	0.9%
J00	Acute nasopharyngitis [common cold]	6	0.5%	4	0.6%	1	0.4%	1	0.4%	0	0.0%

J	38	Diseases of vocal cords and larynx, not elsewhere classified	5	0.4%	3	0.4%		0.0%	2	0.8%	0	0.0%
J	31	Pulmonary edema	5	0.4%	3	0.4%	1	0.4%	0	0.0%	1	0.9%
JE	34	Other interstitial pulmonary diseases	5	0.4%	3	0.4%	1	0.4%	0	0.0%	1	0.9%
J	31	Chronic rhinitis, nasopharyngitis and pharyngitis	5	0.4%	3	0.4%		0.0%	2	0.8%	0	0.0%
J	90	Pleural effusion, not elsewhere classified	4	0.3%	2	0.3%	1	0.4%	1	0.4%	0	0.0%
J2	21	Acute bronchiolitis	3	0.2%	3	0.4%		0.0%	0	0.0%	0	0.0%
J2	42	Unspecified chronic bronchitis	3	0.2%	1	0.1%	1	0.4%	1	0.4%	0	0.0%
JE	30	Acute respiratory distress syndrome	3	0.2%	1	0.1%	1	0.4%	1	0.4%	0	0.0%
J	33	Nasal polyp	2	0.2%		0.0%		0.0%	1	0.4%	1	0.9%
U	09	Post COVID-19 condition	2	0.2%	2	0.3%		0.0%	0	0.0%	0	0.0%
J	93	Pneumothorax and air leak	2	0.2%	2	0.3%		0.0%	0	0.0%	0	0.0%
J2	41	Simple and mucopurulent chronic bronchitis	2	0.2%	1	0.1%		0.0%	1	0.4%	0	0.0%
J	35	Chronic diseases of tonsils and adenoids	2	0.2%	1	0.1%		0.0%	1	0.4%	0	0.0%
J1	15	Bacterial pneumonia, not elsewhere classified	2	0.2%	1	0.1%		0.0%	1	0.4%	0	0.0%
J1	11	Influenza due to unidentified influenza virus	2	0.2%	2	0.3%		0.0%	0	0.0%	0	0.0%
J	05	Acute obstructive laryngitis [croup] and epiglottitis	2	0.2%		0.0%	1	0.4%	1	0.4%	0	0.0%
J	36	Peritonsillar abscess	2	0.2%	1	0.1%	1	0.4%	0	0.0%	0	0.0%
J	95	Intraop and postproc comp and disorders of resp sys, NEC	1	0.1%		0.0%		0.0%	1	0.4%	0	0.0%
E	84	Cystic fibrosis	1	0.1%		0.0%		0.0%	1	0.4%	0	0.0%
J	04	Acute laryngitis and tracheitis	1	0.1%		0.0%		0.0%	1	0.4%	0	0.0%
J2	22	Unspecified acute lower respiratory infection	1	0.1%	1	0.1%		0.0%	0	0.0%	0	0.0%
J	37	Chronic laryngitis and laryngotracheitis	1	0.1%		0.0%		0.0%	1	0.4%	0	0.0%
J	39	Other diseases of upper respiratory tract	1	0.1%		0.0%	1	0.4%	0	0.0%	0	0.0%
J2	47	Bronchiectasis	1	0.1%		0.0%		0.0%	0	0.0%	1	0.9%
Je	69	Pneumonitis due to solids and liquids	1	0.1%		0.0%		0.0%	1	0.4%	0	0.0%
		Total:	1,455	111.0%	825	119.7%	257	94.1%	283	116.9%	90	84.1%

Limitations:

- This study evaluates a short point in time. Prescription claims data are subject to inherent limitations based on the design and may not accurately reflect true medication use. For albuterol, duplicate claims with the intent to store the medication at multiple locations (e.g. home and school) cannot be ascertained.
- Asthma has multiple diagnosis codes with varying severity and condition may wax and wane seasonally and in response to medication adherence.
- Those with more severe asthma may be more likely to have extra inhalers at multiple locations to ensure access, while also more likely to have adverse outcomes due to disease severity.
- Medical claims data and diagnosis codes may be incomplete. Post-hoc analysis of potential indications for SABA use in patients without asthma or COPD diagnoses must be interpreted with caution and is not all-inclusive.
- Inclusion criteria limited ability to follow patients for full year to describe high SABA use as defined by GINA.
- Inclusion limited SABA of interest to inhaler formulations; individuals relying on nebulizer formulations are not reflected.
- A significant portion of patients were excluded based on Medicare and TPL eligibility, and Medicaid eligibility requirements (Table 7).
- Timing of evaluation window likely captured most first claims in fall. Seasonal differences such as wildfire smoke in fall and pollen in spring may affect claims.
- Given high rate of non-asthma diagnoses and differences in number of inhalers seen in subgroups with and without asthma or COPD, the outcome groups compared in **Table 5** are likely fundamentally different patient populations.

Table 7. Population of included patients

Number of	included	patients

Members with FFS paid claims for a SABA	5,846
After 6 month baseline Medicaid eligibility requirement	3,222 2,427
After 6 month follow-up FFS eligibility requirement	1,867

References:

- 1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated May 2023. Available from: <u>www.ginasthma.org</u>. Accessed June 8, 2023.
- 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from: <u>www.ginasthma.org</u>. Accessed June 8, 2023.
- 3. Chipps BE, Murphy KR, Oppenheimer J. 2020 NAEPP Guidelines Update and GINA 2021-Asthma Care Differences, Overlap, and Challenges. J Allergy Clin Immunol Pract. 2022;10(1S):S19-S30.
- 4. Agusti A, Celli BR, Criner GJ, et al. Global Initiative for Chronic Obstructive Lung Disease 2023 Report: GOLD Executive Summary. *Am J Respir Crit Care Med.* 2023;207(7):819-837.

Short-Acting Beta Agonist Inhaler-Quantity Limit

Goal(s):

• Restrict use of short-acting beta agonist inhalers (SABA) inhalers to reduce overuse and risk of harmful outcomes as supported by medical literature for patients with asthma.

Length of Authorization:

• Up to 12 months

Requires PA:

- Any SABA claim for more than 6 claims in 6 months.
- Auto-PA patients with chronic obstructive pulmonary disease (COPD) and certain asthma controller medications.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
- Searchable site for Oregon FFS Drug Class listed at <u>www.orpdl.org/drugs/</u>

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Does the patient have a diagnosis of COPD?	Yes: Approve for 12 months	No: Go to #3
3. Does the patient have a diagnosis of asthma?	Yes : Go to #4	No: Go to #5
 Does prescriber agree to add a controller therapy or discuss adherence with patient for prescribed controller? Inform prescriber of preferred agents in classes. 	Yes : Approve for 6 months	No: Pass to RPh. Deny; medical appropriateness.
Note: Inhaled corticosteroids are preferred controller for most patients with asthma. Combinations with long-acting beta agonists, inhaled muscarinics, leukotriene modifiers, or biologic agents may be appropriate for some patients with asthma or COPD.		

Approval Criteria		
5. Is the request from a pulmonary or allergy specialist?	Yes: Approve for 12 months	No: Go to #6
6. Is the request for a single inhaler for an acute condition?	Yes: Approve single inhaler. Chronic use requires a specialist or diagnosis of asthma or COPD with concomitant use of a guideline directed controller medication.	No: Pass to RPh. Deny; medical appropriateness.



10/23 (SF) <u>TBD</u>

Long-acting Beta-agonists (LABA)

Goals:

• To optimize the safe and effective use of LABA therapy in patients with asthma and COPD.

Length of Authorization:

• Up to 12 months

Requires PA:

• Non-preferred LABA products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
- Searchable site for Oregon FFS Drug Class listed at <u>www.orpdl.org/drugs/</u>

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 Code	
2. Will the prescriber consider a change to a preferred product?	Yes: Inform prescriber of covered alternatives in class	No: Go to #3
Message:		
 Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy an Therapeutics (P&T) Committee. 	d	
3. Does the patient have a diagnosis of asthma or reactive airw disease?	ay Yes: Go to #5	No: Go to #4
4. Does the patient have a diagnosis of COPD, mucopurulent chronic bronchitis and/or emphysema?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness.
		Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded
5. Does the patient have an active prescription for an inhaled corticosteroid (ICS) or an alternative asthma controller medication?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: <u>10/23 (SF);</u> 10/22 (KS), 10/20 (KS), 5/19 (KS); 1/18; 9/16; 9/15); 5/12; 9/09; 5/09

Long-acting Muscarinic Antagonist/Long-acting Beta-agonist (LAMA/LABA) and LAMA/LABA/Inhaled Corticosteroid (LAMA/LABA/ICS) Combinations

Goals:

- To optimize the safe and effective use of LAMA/LABA/ICS therapy in patients with asthma and COPD.
- Step-therapy required prior to coverage:
 - Asthma and COPD: short-acting bronchodilator and previous trial of two drug combination therapy (ICS/LABA, LABA/LAMA or ICS/LAMA). Preferred monotherapy inhaler LAMA and LABA products do NOT require prior authorization.

Length of Authorization:

• Up to 12 months

Requires PA:

• All LAMA/LABA and LAMA/LABA/ICS products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
- Searchable site for Oregon FFS Drug Class listed at <u>www.orpdl.org/drugs/</u>

Approval Criteria	
1. What diagnosis is being treated?	Record ICD10 Code

Ap	oproval Criteria		
2.	 Will the prescriber consider a change to a preferred product? <u>Message</u>: Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. 	Yes: Inform prescriber of preferred LAMA and LABA products in each class	No: Go to #3
3.	Does the patient have a diagnosis of asthma or reactive airway disease without COPD?	Yes: Go to #8	No: Go to #4
4.	Does the patient have a diagnosis of COPD, mucopurulent chronic bronchitis and/or emphysema?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded.
5.	Is the request for a LAMA/LABA combination product?	Yes: Approve for up to 12 months. Stop coverage of all other LAMA and LABA inhalers or scheduled SAMA/SABA inhalers (PRN SABA or SAMA permitted).	No: Go to #6
6.	Is the request for a 3 drug ICS/LABA/LAMA combination product and is there a documented trial of a LAMA and LABA, or ICS and LABA or ICS and LAMA?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness.

Ap	oproval Criteria		
7.	Is there documentation that the prescriber is willing to stop coverage of all other LAMA, LABA, and ICS inhaler combination products?	Yes: Approve for up to 12 months. Stop coverage of all other LAMA, LABA and ICS inhalers.	No: Pass to RPh. Deny; medical appropriateness.
8.	Does the patient have an active prescription for an on-demand short-acting acting beta-agonist (SABA) and/or for ICS-formoterol?	Yes: Go to #9	No: Pass to RPh. Deny; medical appropriateness.
9.	Is the request for Trelegy Ellipta (ICS/LAMA/LABA) combination product and is there a documented trial of an ICS/LABA?	Yes: Approve for up to 12 months. Stop coverage of all other LAMA, LABA and ICS inhalers (with the exception of ICS-formoterol which may be continued)	No: Pass to RPh. Deny; medical appropriateness.

P&T Review: <u>10/23 (SF);</u> 10/22 (KS), 10/21 (SF); 12/20 (KS), 10/20, 5/19; 1/18; 9/16; 11/15; 9/15; 11/14; 11/13; 5/12; 9/09; 2/06

Implementation: 1/1/21; 3/1/18; 10/13/16; 1/1/16; 1/15; 1/14; 9/12; 1/10

Inhaled Corticosteroids (ICS)

<u>Goals:</u>

• To optimize the safe and effective use of ICS therapy in patients with asthma and COPD.

Length of Authorization:

• Up to 12 months

Requires PA:

Author: Fletcher

• Non-preferred ICS products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
 Searchable site for Oregon FFS Drug Class listed at <u>www.orpdl.org/drugs/</u>

Ap	oproval Criteria		
1.	What diagnosis is being treated?	Record ICD10 Code	
2.	Will the prescriber consider a change to a preferred product? <u>Message</u> : Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	Yes: Inform prescriber of covered alternatives in class.	No: Go to #3
3.	Is the request for treatment of asthma or reactive airway disease?	Yes: Go to #6	No: Go to #4
4.	Is the request for treatment of COPD, mucopurulent chronic bronchitis and/or emphysema?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded.

Ар	proval Criteria		
5.	Does the patient have an active prescription for an inhaled long- acting bronchodilator (anticholinergic or beta-agonist)?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness.
6.	Does the patient have an active prescription for an on-demand short-acting beta-agonist (SABA) or an alternative rescue medication for acute asthma exacerbations?	Yes: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: <u>10/23 (SF);</u> 10/22 (KS), 10/20 (KS), 5/19 (KS), 1/18; 9/16; 9/15

Implementation: 3/1/18; 10/13/16; 10/9/15

Appendix 2: Drug classes and ICD 10 coding

Table A. Anticholinergic Inhalers

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
B60	000057	021700	INHALATION	SOLUTION	IPRATROPIUM BROMIDE	ipratropium bromide	Y
B60	000057	021700	INHALATION	SOLUTION	IPRATROPIUM BROMIDE	ipratropium bromide	Y
B60	000057	059081	INHALATION	HFA AER AD	ATROVENT HFA	ipratropium bromide	Y
B60	000057	059081	INHALATION	HFA AER AD	ATROVENT HFA	ipratropium bromide	Y
B61	024024	050714	INHALATION	CAP W/DEV	SPIRIVA HANDIHALER	tiotropium bromide	Y
B61	024024	063164	INHALATION	MIST INHAL	SPIRIVA RESPIMAT	tiotropium bromide	Y
B61	024024	074813	INHALATION	MIST INHAL	SPIRIVA RESPIMAT	tiotropium bromide	Y
B61	039528	069855	INHALATION	AER POW BA	TUDORZA PRESSAIR	aclidinium bromide	Ν
B61	041115	072375	INHALATION	BLST W/DEV	INCRUSE ELLIPTA	umeclidinium bromide	Y
B61	044687	078007	INHALATION	VIAL-NEB	LONHALA MAGNAIR STARTER	glycopyrrol/nebulizer/accessor	N
B61	044691	078010	INHALATION	VIAL-NEB	LONHALA MAGNAIR REFILL	glycopyrrolate/neb.accessories	N
B61	045477	079272	INHALATION	VIAL-NEB	YUPELRI	revefenacin	Ν
B62	009040	048018	INHALATION	AMPUL-NEB	DUONEB	ipratropium/albuterol sulfate	Y
B62	009040	048018	INHALATION	AMPUL-NEB	IPRATROPIUM- ALBUTEROL	ipratropium/albuterol sulfate	Y

B62	009040	048018	INHALATION	AMPUL-NEB	IPRATROPIUM- ALBUTEROL	ipratropium/albuterol sulfate	Y
B62	009040	069371	INHALATION	MIST INHAL	COMBIVENT RESPIMAT	ipratropium/albuterol sulfate	Y

Table B. Long-Acting Beta Agonists

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
B6Y	007393	031417	INHALATION	BLST W/DEV	SEREVENT DISKUS	salmeterol xinafoate	Y
B6Y	010747	063016	INHALATION	VIAL-NEB	FORMOTEROL FUMARATE	formoterol fumarate	Ν
B6Y	010747	063016	INHALATION	VIAL-NEB	FORMOTEROL FUMARATE	formoterol fumarate	Ν
B6Y	010747	063016	INHALATION	VIAL-NEB	PERFOROMIST	formoterol fumarate	Ν
B6Y	034087	061579	INHALATION	VIAL-NEB	ARFORMOTEROL TARTRATE	arformoterol tartrate	Ν
B6Y	034087	061579	INHALATION	VIAL-NEB	BROVANA	arformoterol tartrate	Ν
B6Z	040969	072077	INHALATION	MIST INHAL	STRIVERDI RESPIMAT	olodaterol HCI	Ν

Table C. Short Acting Beta Agonists

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
B6W	002058	004964	INHALATION	SOLUTION	ALUPENT	metaproterenol	Ν
						sulfate	
<mark>B6W</mark>	<mark>002058</mark>	<mark>016033</mark>	INHALATION	AER	ALUPENT	metaproterenol	N
				W/ADAP		sulfate	
B6W	002073	005039	INHALATION	VIAL-NEB	AIRET	albuterol sulfate	Y
B6W	002073	005039	INHALATION	VIAL-NEB	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	005039	INHALATION	VIAL-NEB	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	005040	INHALATION	SOLUTION	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	005040	INHALATION	SOLUTION	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	005040	INHALATION	SOLUTION	PROVENTIL	albuterol sulfate	Y
B6W	002073	005040	INHALATION	SOLUTION	VENTOLIN	albuterol sulfate	Y
B6W	<mark>002073</mark>	<mark>028090</mark>	INHALATION	HFA AER	ALBUTEROL SULFATE HFA	albuterol sulfate	Y
				<mark>AD</mark>			
<mark>B6W</mark>	<mark>002073</mark>	<mark>028090</mark>	INHALATION	HFA AER	ALBUTEROL SULFATE HFA	albuterol sulfate	Y
				<mark>AD</mark>			
B6W	<mark>002073</mark>	<mark>028090</mark>	INHALATION	HFA AER	PROAIR HFA	albuterol sulfate	Y
				AD			
<mark>B6W</mark>	002073	<mark>028090</mark>	INHALATION	HFA AER	PROAIR HFA	albuterol sulfate	Y
				AD			

<mark>B6W</mark>	<mark>002073</mark>	028090	INHALATION	HFA AER	PROVENTIL HFA	albuterol sulfate	Y
B6W	002073	028090			PROVENTIL HEA	albuterol sulfate	Y
				AD			
<mark>B6W</mark>	<mark>002073</mark>	<mark>028090</mark>	INHALATION	<mark>HFA AER</mark>	VENTOLIN HFA	albuterol sulfate	Y
Della				AD			
B6W	002073	<mark>028090</mark>	INHALATION		VENTOLIN HFA	albuterol sulfate	Y
B6W	002073	048698	INHALATION	VIAI -NFB	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	048699	INHALATION	VIAL-NEB		albuterol sulfate	Ŷ
B6W	002073	054687	INHALATION	VIAL-NEB	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	054687	INHALATION	VIAL-NEB	ALBUTEROL SULFATE	albuterol sulfate	Y
B6W	002073	<mark>073806</mark>	INHALATION	AER POW	PROAIR RESPICLICK	albuterol sulfate	N
				BA			
<mark>B6W</mark>	<mark>002073</mark>	<mark>080260</mark>	INHALATION	AER PW	PROAIR DIGIHALER	albuterol sulfate	N
DCM	000074	005007		BAS		alleutaral	NI
	002074	005037		AEROSOL			N
	002074	005037					N
DOVV	<u>002074</u>	000000			ALBOTEROL	abuteror	
B6W	019858	041848	INHALATION	VIAL-NEB	LEVALBUTEROL HCL	levalbuterol HCI	Ν
B6W	019858	041848	INHALATION	VIAL-NEB	LEVALBUTEROL HCL	levalbuterol HCI	Ν
B6W	019858	041848	INHALATION	VIAL-NEB	XOPENEX	levalbuterol HCI	Ν
B6W	019858	041848	INHALATION	VIAL-NEB	XOPENEX	levalbuterol HCI	Ν
B6W	019858	041849	INHALATION	VIAL-NEB	LEVALBUTEROL HCL	levalbuterol HCI	Ν
B6W	019858	041849	INHALATION	VIAL-NEB	XOPENEX	levalbuterol HCI	Ν
B6W	019858	049871	INHALATION	VIAL-NEB	LEVALBUTEROL HCL	levalbuterol HCI	Ν
B6W	019858	049871	INHALATION	VIAL-NEB	XOPENEX	levalbuterol HCI	Ν
B6W	019858	057879	INHALATION	VIAL-NEB	LEVALBUTEROL	levalbuterol HCI	Ν
D6W/	010959	057970				lovalbutaral HCI	N
	019000	057079					
DOVV	032014	000090			LEVALBUIEROL TARTRATE HFA		
B6W	032814	058890	INHALATION	HFA AER	LEVALBUTEROL TARTRATE HFA	levalbuterol tartrate	N
				AD			
B6W	<mark>032814</mark>	<mark>058890</mark>	INHALATION	HFA AER	XOPENEX HFA	levalbuterol tartrate	N
				AD			

Note: Only highlighted agents are inhaler formulations

Table D. Combination Inhalers: Long-acting muscarinic, Long Acting Beta Agonist, and/or Inhaled Corticosteroids

HIC3 HSN GSN RouteDesc FormDes	c Brand	Generic	PDL
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B62	040852	071883	INHALATION	BLST W/DEV	ANORO ELLIPTA	umeclidinium brm/vilanterol tr	Y
B62	041692	073344	INHALATION	AER POW BA	DUAKLIR PRESSAIR	aclidinium brom/formoterol fum	N
B62	042048	074131	INHALATION	MIST INHAL	STIOLTO RESPIMAT	tiotropium Br/olodaterol HCI	Y
B62	043352	075984	INHALATION	HFA AER AD	BEVESPI AEROSPHERE	glycopyrrolate/formoterol fum	N
<mark>B64</mark>	<mark>044508</mark>	<mark>077780</mark>	INHALATION	<mark>BLST</mark> W/DEV	TRELEGY ELLIPTA	fluticasone/umeclidin/vilanter	N
<mark>B64</mark>	<mark>044508</mark>	<mark>081555</mark>	INHALATION	BLST W/DEV	TRELEGY ELLIPTA	fluticasone/umeclidin/vilanter	N
<mark>B64</mark>	<mark>046753</mark>	<mark>081351</mark>	INHALATION	<mark>HFA AER</mark> AD	BREZTRI AEROSPHERE	budesonide/glycopyr/formoterol	N

Note: Only highlighted agents include inhaled corticosteroids (ICS)

Table E. Long Acting Beta Agonists and Inhaled Corticosteroid combinations

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
B63	019963	043366	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043366	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043366	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043366	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043366	INHALATION	BLST W/DEV	WIXELA INHUB	fluticasone propion/salmeterol	Y
B63	019963	043367	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043367	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043367	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043367	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043367	INHALATION	BLST W/DEV	WIXELA INHUB	fluticasone propion/salmeterol	Y
B63	019963	043368	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043368	INHALATION	BLST W/DEV	ADVAIR DISKUS	fluticasone propion/salmeterol	Y
B63	019963	043368	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043368	INHALATION	BLST W/DEV	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	043368	INHALATION	BLST W/DEV	WIXELA INHUB	fluticasone propion/salmeterol	Y
B63	019963	061343	INHALATION	HFA AER AD	ADVAIR HFA	fluticasone propion/salmeterol	Y
B63	019963	061343	INHALATION	HFA AER AD	FLUTICASONE-SALMETEROL HFA	fluticasone propion/salmeterol	Y
B63	019963	061344	INHALATION	HFA AER AD	ADVAIR HFA	fluticasone propion/salmeterol	Y
B63	019963	061344	INHALATION	HFA AER AD	FLUTICASONE-SALMETEROL HFA	fluticasone propion/salmeterol	Y
B63	019963	061345	INHALATION	HFA AER AD	ADVAIR HFA	fluticasone propion/salmeterol	Υ
B63	019963	061345	INHALATION	HFA AER AD	FLUTICASONE-SALMETEROL HFA	fluticasone propion/salmeterol	Y
B63	019963	077072	INHALATION	AER POW BA	AIRDUO RESPICLICK	fluticasone propion/salmeterol	Y

B63	019963	077072	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	077072	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	077073	INHALATION	AER POW BA	AIRDUO RESPICLICK	fluticasone propion/salmeterol	Y
B63	019963	077073	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	077073	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	077074	INHALATION	AER POW BA	AIRDUO RESPICLICK	fluticasone propion/salmeterol	Y
B63	019963	077074	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	077074	INHALATION	AER POW BA	FLUTICASONE-SALMETEROL	fluticasone propion/salmeterol	Y
B63	019963	081399	INHALATION	AER PW BAS	AIRDUO DIGIHALER	fluticasone propion/salmeterol	Ν
B63	019963	081400	INHALATION	AER PW BAS	AIRDUO DIGIHALER	fluticasone propion/salmeterol	Ν
B63	019963	081401	INHALATION	AER PW BAS	AIRDUO DIGIHALER	fluticasone propion/salmeterol	Ν
B63	021993	062725	INHALATION	HFA AER AD		budesonide/formoterol	Y
DCO	001000	000705					V
D03	021993	002725	INHALATION		FUMARATE	fumarate	ř
B63	021993	062725	INHALATION	HFA AER AD	SYMBICORT	budesonide/formoterol	Y
						fumarate	
B63	021993	062726	INHALATION	HFA AER AD	BUDESONIDE-FORMOTEROL FUMARATE	budesonide/formoterol fumarate	Y
B63	021993	062726	INHALATION	HFA AER AD	BUDESONIDE-FORMOTEROL	budesonide/formoterol	Y
					FUMARATE	fumarate	
B63	021993	062726	INHALATION	HFA AER AD	SYMBICORT	budesonide/formoterol fumarate	Y
B63	037050	066480	INHALATION	HFA AER AD	DULERA	mometasone/formoterol	Y
B63	037050	066481	INHALATION	HFA AER AD	DULERA	mometasone/formoterol	Υ
B63	037050	067555	INHALATION	HFA AER AD	DULERA	mometasone/formoterol	Y
B63	040319	070972	INHALATION	BLST W/DEV	BREO ELLIPTA	fluticasone/vilanterol	N
B63	040319	070972	INHALATION	BLST W/DEV	FLUTICASONE-VILANTEROL	fluticasone/vilanterol	N
B63	040319	071815	INHALATION	BLST W/DEV	BREO ELLIPTA	fluticasone/vilanterol	N
B63	040319	071815	INHALATION	BLST W/DEV	FLUTICASONE-VILANTEROL	fluticasone/vilanterol	Ν

Table F. Inhaled Corticosteroids

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
B6M	000070	077643	INHALATION	HFA AEROBA	QVAR REDIHALER	beclomethasone dipropionate	N
B6M	000070	077644	INHALATION	HFA AEROBA	QVAR REDIHALER	beclomethasone dipropionate	N
B6M	000070	077644	INHALATION	HFA AEROBA	QVAR REDIHALER	beclomethasone dipropionate	N

B6M	000072	000213	INHALATION	AER W/ADAP	AEROBID	flunisolide	N
B6M	002891	000212	INHALATION	AER W/ADAP	AZMACORT	triamcinolone	Ν
						acetonide	
B6M	003329	051649	INHALATION	AER POW BA	ASMANEX	mometasone	Y
						furoate	
B6M	003329	059326	INHALATION	AER POW BA	ASMANEX	mometasone	Y
DCM	000000	050000				furoate	V
BOIN	003329	059326	INHALATION	AER POW BA	ASMANEX	furcate	ř
B6M	003329	059327		AFR POW BA		mometasone	Y
Dom	000020	000021				furoate	· ·
B6M	003329	059328	INHALATION	AER POW BA	ASMANEX	mometasone	Y
						furoate	
B6M	003329	064010	INHALATION	AER POW BA	ASMANEX	mometasone	Y
						furoate	
B6M	003329	073197	INHALATION	HFA AER AD	ASMANEX HFA	mometasone	N
Dali		070400				furoate	
B6M	003329	073198	INHALATION	HFA AER AD	ASMANEX HFA	mometasone	N
DGM	002220	090660					N
DOIVI	003329	000009			ASIMANEA HFA	furoate	
B6M	006545	018165	INHALATION	AMPUI -NEB	BUDESONIDE	budesonide	N
B6M	006545	018165		AMPUL-NEB	PULMICORT	budesonide	N
B6M	006545	046525		AMPUL-NEB	BUDESONIDE	budesonide	N
B6M	006545	046525	INHALATION	AMPUL-NEB	PULMICORT	budesonide	N
B6M	006545	046525		AMPUL-NEB	PULMICORT	budesonide	N
B6M	006545	046526		AMPUL-NEB	BUDESONIDE	budesonide	N
B6M	006545	046526		AMPUL-NEB	PULMICORT	budesonide	N
B6M	006545	046526		AMPUL-NEB	PULMICORT	budesonide	N
B6M	006545	062240		AFR POW BA	PULMICORT FLEXHALER	budesonide	Y
B6M	006545	062241		AFR POW BA		budesonide	Y
B6M	006545	062241		AFR POW BA		budesonide	Y
B6M	006607	017184		AFR W/ADAP	AFROBID-M	flunisolide/menthol	N
B6M	007873	019317		BLST W/DEV		fluticasone	V
DOIN	00/0/0	010017	INTALATION	DEGTWIDEV		propionate	1
B6M	007873	019317	INHALATION	BLST W/DEV	FLOVENT DISKUS	fluticasone	Y
						propionate	
B6M	007873	019318	INHALATION	BLST W/DEV	FLOVENT DISKUS	fluticasone	Y
						propionate	
B6M	007873	019319	INHALATION	BLST W/DEV	FLOVENT DISKUS	fluticasone	Y
Dati		0040-i				propionate	
B6M	007873	021251	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Y
						propionate	

B6M	007873	021251	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Y
						propionate	
B6M	007873	021251	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Υ
						propionate	
B6M	007873	021251	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Y
						propionate	
B6M	007873	021253	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Υ
						propionate	
B6M	007873	021253	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Υ
						propionate	
B6M	007873	021253	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Υ
						propionate	
B6M	007873	021253	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Y
						propionate	
B6M	007873	021483	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Υ
						propionate	
B6M	007873	021483	INHALATION	AER W/ADAP	FLOVENT HFA	fluticasone	Y
						propionate	
B6M	007873	021483	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Y
						propionate	
B6M	007873	021483	INHALATION	AER W/ADAP	FLUTICASONE PROPIONATE HFA	fluticasone	Y
						propionate	
B6M	007873	081476	INHALATION	AER PW BAS	ARMONAIR DIGIHALER	fluticasone	N
						propionate	
B6M	007873	081478	INHALATION	AER PW BAS	ARMONAIR DIGIHALER	fluticasone	N
						propionate	
B6M	007873	081485	INHALATION	AER PW BAS	ARMONAIR DIGIHALER	fluticasone	Ν
						propionate	
B6M	032691	058671	INHALATION	HFA AER AD	ALVESCO	ciclesonide	Ν
B6M	032691	058672	INHALATION	HFA AER AD	ALVESCO	ciclesonide	Ν
B6M	034756	072722	INHALATION	BLST W/DEV	ARNUITY ELLIPTA	fluticasone furoate	N
B6M	034756	072723	INHALATION	BLST W/DEV	ARNUITY ELLIPTA	fluticasone furoate	Ν
B6M	034756	078449	INHALATION	BLST W/DEV	ARNUITY ELLIPTA	fluticasone furoate	Ν

Table G. Therapeutic Immune Modulators For Asthma and Atopic Dermatitis

HIC3	HSN	GSN	RouteDesc	FormDesc	Brand	Generic	PDL
V4D	044180	077263	SUBCUT	SYRINGE	DUPIXENT SYRINGE	dupilumab	N
V4D	044180	079179	SUBCUT	SYRINGE	DUPIXENT SYRINGE	dupilumab	Ν
V4D	044180	081231	SUBCUT	PEN INJCTR	DUPIXENT PEN	dupilumab	N
V4D	044180	081615	SUBCUT	PEN INJCTR	DUPIXENT PEN	dupilumab	N
V4D	044180	082769	SUBCUT	SYRINGE	DUPIXENT SYRINGE	dupilumab	Ν

V4F	047740	082944	SUBCUT	SYRINGE	TEZSPIRE	tezepelumab-ekko	Ν
V4F	047740	084017	SUBCUT	PEN INJCTR	TEZSPIRE	tezepelumab-ekko	N
V4G	047741	082945	SUBCUT	SYRINGE	ADBRY	tralokinumab-ldrm	Ν
Z20	042775	075111	SUBCUT	VIAL	NUCALA	mepolizumab	N
Z20	042775	079828	SUBCUT	SYRINGE	NUCALA	mepolizumab	N
Z20	042775	079829	SUBCUT	AUTO INJCT	NUCALA	mepolizumab	Ν
Z20	042775	083454	SUBCUT	SYRINGE	NUCALA	mepolizumab	N
Z20	043211	075753	INTRAVEN	VIAL	CINQAIR	reslizumab	Ν
Z23	044635	077921	SUBCUT	SYRINGE	FASENRA	benralizumab	N
Z23	044635	080268	SUBCUT	AUTO INJCT	FASENRA PEN	benralizumab	N
Z2L	025399	052758	SUBCUT	VIAL	XOLAIR	omalizumab	Ν
Z2L	025399	067907	SUBCUT	SYRINGE	XOLAIR	omalizumab	Ν
Z2L	025399	067908	SUBCUT	SYRINGE	XOLAIR	omalizumab	N
Z2Z	047767	082989	ORAL	TABLET	CIBINQO	abrocitinib	Ν
Z2Z	047767	082990	ORAL	TABLET	CIBINQO	abrocitinib	N
Z2Z	047767	082991	ORAL	TABLET	CIBINQO	abrocitinib	Ν

Table H. Oral Glucocorticoids

HIC3	HSN	GSN	Route	Form	Brand	Generic	PDL
P5A	002860	006685	ORAL	TABLET	CORTISONE ACETATE	cortisone acetate	Y
P5A	002867	006703	ORAL	TABLET	CORTEF	hydrocortisone	Y
P5A	002867	006703	ORAL	TABLET	HYDROCORTISONE	hydrocortisone	Y
P5A	002867	006704	ORAL	TABLET	CORTEF	hydrocortisone	Y
P5A	002867	006704	ORAL	TABLET	HYDROCORTISONE	hydrocortisone	Y
P5A	002867	006705	ORAL	TABLET	CORTEF	hydrocortisone	Y
P5A	002867	006705	ORAL	TABLET	HYDROCORTISONE	hydrocortisone	Y
P5A	002874	006719	ORAL	SOLUTION	PREDNISOLONE	prednisolone	Y
P5A	002877	006737	ORAL	TABLET	MEDROL	methylprednisolone	Y
P5A	002877	006737	ORAL	TABLET	METHYLPREDNISOLONE	methylprednisolone	Y
P5A	002877	006738	ORAL	TABLET	MEDROL	methylprednisolone	Y
P5A	002877	006739	ORAL	TABLET	MEDROL	methylprednisolone	Y
P5A	002877	006740	ORAL	TABLET	METHYLPREDNISOLONE	methylprednisolone	Y
P5A	002877	006741	ORAL	TABLET	MEDROL	methylprednisolone	Y
P5A	002877	006741	ORAL	TABLET	METHYLPREDNISOLONE	methylprednisolone	Y
P5A	002877	006742	ORAL	TABLET	MEDROL	methylprednisolone	Y
P5A	002877	006742	ORAL	TABLET	METHYLPREDNISOLONE	methylprednisolone	Y
P5A	002877	045311	ORAL	TAB DS PK	MEDROL	methylprednisolone	Y

P5A	002877	045311	ORAL	TAB DS PK	METHYLPREDNISOLONE	methylprednisolone	Y
P5A	002879	006745	ORAL	ORAL CONC	PREDNISONE INTENSOL	prednisone	Y
P5A	002879	006746	ORAL	SOLUTION	PREDNISONE	prednisone	Υ
P5A	002879	006748	ORAL	TABLET	PREDNISONE	prednisone	Υ
P5A	002879	006749	ORAL	TABLET	PREDNISONE	prednisone	Y
P5A	002879	006750	ORAL	TABLET	PREDNISONE	prednisone	Y
P5A	002879	006751	ORAL	TABLET	PREDNISONE	prednisone	Υ
P5A	002879	006753	ORAL	TABLET	PREDNISONE	prednisone	Y
P5A	002879	006754	ORAL	TABLET	PREDNISONE	prednisone	Y
P5A	002879	045267	ORAL	TAB DS PK	PREDNISONE	prednisone	Y
P5A	002879	045268	ORAL	TAB DS PK	PREDNISONE	prednisone	Y
P5A	002879	069864	ORAL	TABLET DR	RAYOS	prednisone	Y
P5A	002879	069865	ORAL	TABLET DR	RAYOS	prednisone	Y
P5A	002879	069866	ORAL	TABLET DR	RAYOS	prednisone	Y
P5A	002889	006780	ORAL	ELIXIR	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006781	ORAL	SOLUTION	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006782	ORAL	DROPS	DEXAMETHASONE INTENSOL	dexamethasone	Y
P5A	002889	006784	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006785	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006786	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006787	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006788	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006789	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	006790	ORAL	TABLET	DEXAMETHASONE	dexamethasone	Y
P5A	002889	045306	ORAL	TAB DS PK	DEXAMETHASONE	dexamethasone	Y
P5A	002889	046463	ORAL	TAB DS PK	DEXAMETHASONE	dexamethasone	Y
P5A	002889	061392	ORAL	TAB DS PK	DEXAMETHASONE	dexamethasone	Y
P5A	002889	064893	ORAL	TAB DS PK	DEXAMETHASONE	dexamethasone	Y
P5A	002889	064893	ORAL	TAB DS PK	TAPERDEX	dexamethasone	Y

P5A	002889	077133	ORAL	TAB DS PK	TAPERDEX	dexamethasone	Y
P5A	002889	077745	ORAL	TAB DS PK	TAPERDEX	dexamethasone	Y
P5A	002867	079919	ORAL	CAP SPRINK	ALKINDI SPRINKLE	hydrocortisone	Ν
P5A	002867	079920	ORAL	CAP SPRINK	ALKINDI SPRINKLE	hydrocortisone	N
P5A	002867	079921	ORAL	CAP SPRINK	ALKINDI SPRINKLE	hydrocortisone	N
P5A	002867	079922	ORAL	CAP SPRINK	ALKINDI SPRINKLE	hydrocortisone	N
P5A	002871	038375	ORAL	SOLUTION	PEDIAPRED	prednisolone sodium phosphate	N
P5A	002871	038375	ORAL	SOLUTION	PREDNISOLONE SODIUM PHOSPHATE	prednisolone sodium phosphate	N
P5A	002871	041424	ORAL	SOLUTION	PREDNISOLONE SODIUM PHOSPHATE	prednisolone sodium phosphate	N
P5A	002871	047282	ORAL	SOLUTION	PREDNISOLONE SODIUM PHOSPHATE	prednisolone sodium phosphate	N
P5A	002871	060956	ORAL	TAB RAPDIS	PREDNISOLONE SODIUM PHOS ODT	prednisolone sodium phosphate	Ν
P5A	002871	060957	ORAL	TAB RAPDIS	PREDNISOLONE SODIUM PHOS ODT	prednisolone sodium phosphate	N
P5A	002871	060958	ORAL	TAB RAPDIS	PREDNISOLONE SODIUM PHOS ODT	prednisolone sodium phosphate	N
P5A	002871	063898	ORAL	SOLUTION	PREDNISOLONE SODIUM PHOSPHATE	prednisolone sodium phosphate	N
P5A	002871	064528	ORAL	SOLUTION	PREDNISOLONE SODIUM PHOSPHATE	prednisolone sodium phosphate	N
P5A	002874	006721	ORAL	TABLET	MILLIPRED	prednisolone	Ν
P5A	002874	006721	ORAL	TABLET	PREDNISOLONE	prednisolone	Ν
P5A	002889	080270	ORAL	TABLET	HEMADY	dexamethasone	Ν

Table I. Leukotriene Modifiers

HIC3	HSN	GSN	Route	Form	Brand	Generic	PDL
Z4B	016911	037003	ORAL	TAB	MONTELUKAST	montelukast	Y
				CHEW	SODIUM	sodium	
Z4B	016911	037003	ORAL	TAB	SINGULAIR	montelukast	Y
				CHEW		sodium	

Z4B	016911	038451	ORAL	TABLET	MONTELUKAST	montelukast	Y
74P	016011	029451				sodium	V
Z4D	010911	030451	UNAL	TABLET	SINGULAIN	sodium	I
Z4B	016911	044803	ORAL	ТАВ	MONTELUKAST	montelukast	Y
			••••	CHEW	SODIUM	sodium	
Z4B	016911	044803	ORAL	ТАВ	SINGULAIR	montelukast	Y
				CHEW		sodium	
<mark>Z2X</mark>	<mark>037123</mark>	<mark>066612</mark>	ORAL	TABLET	DALIRESP	roflumilast	N
<mark>Z2X</mark>	<mark>037123</mark>	<mark>066612</mark>	ORAL	TABLET	ROFLUMILAST	roflumilast	N
<mark>Z2X</mark>	<mark>037123</mark>	<mark>078213</mark>	ORAL	TABLET	DALIRESP	roflumilast	N
<mark>Z2X</mark>	<mark>037123</mark>	<mark>078213</mark>	ORAL	TABLET	ROFLUMILAST	roflumilast	N
Z4B	011815	027962	ORAL	TABLET	ACCOLATE	zafirlukast	Ν
Z4B	011815	027962	ORAL	TABLET	ZAFIRLUKAST	zafirlukast	Ν
Z4B	011815	043557	ORAL	TABLET	ACCOLATE	zafirlukast	Ν
Z4B	011815	043557	ORAL	TABLET	ZAFIRLUKAST	zafirlukast	Ν
Z4B	016911	051512	ORAL	GRAN	MONTELUKAST	montelukast	Ν
				PACK	SODIUM	sodium	
Z4B	016911	051512	ORAL	GRAN	SINGULAIR	montelukast	Ν
				PACK		sodium	
Z4E	012321	029803	ORAL	TABLET	ZYFLO	zileuton	Ν
Z4E	012321	063062	ORAL	ТВМР	ZILEUTON ER	zileuton	N
				12HR			
<mark>Z2X</mark>	<mark>037123</mark>	<mark>078213</mark>	ORAL	TABLET	ROFLUMILAST	roflumilast	

Note: roflumilast is indicated only for COPD and was not included in the definition for leukotriene modifiers

Table J. ICD 10 codes of Interest

Diagnosis	ICD-10 Code-CM code			
Asthma	J45.x			
Asthma Types				
Mild intermittent asthma	J45.2x			
Mild persistent asthma	J45.3x			
Moderate persistent asthma	J45.4x			
Severe persistent asthma	J45.5x			
Other and unspecified asthma	J45.5x			
Other asthma (includes exercised induced	J45.9x			
bronchospasm)				
Comorbidities				
Chronic Obstructive Pulmonary Disease	J44.x			

Table K. Package sizes for asthma inhalers

NameDrugGen	NameDrugBrand	QuanSizeDrugPkg	TextDrugStr	GSN
albuterol sulfate	ALBUTEROL SULFATE HFA	6.7	90 mcg	28090
albuterol sulfate	PROVENTIL HFA	6.7	90 mcg	28090
albuterol sulfate	ALBUTEROL SULFATE HFA	7	90 mcg	28090
albuterol sulfate	VENTOLIN HFA	8	90 mcg	28090
albuterol sulfate	ALBUTEROL SULFATE HFA	8.5	90 mcg	28090
albuterol sulfate	PROAIR HFA	8.5	90 mcg	28090
albuterol sulfate	ALBUTEROL SULFATE HFA	18	90 mcg	28090
albuterol sulfate	VENTOLIN HFA	18	90 mcg	28090

Table L. ICD-10 codes of interest for post-hoc assessment of patients without asthma or chronic obstructive pulmonary disease

Diagnosis	ICD-10 Code-CM code			
Diseases of respiratory system	xL			
Provisional assignment of new disease of uncertain etiology or emergency use	U00-U85			
Personal history of Covid-19	Z86.16			
Viral infection of unspecified site	B34x			
Sleep apnea	G473x			
Tobacco use and nicotine dependence	Z72.0 and F17x			
Cystic fibrosis	E.84.x			
R codes: Symptoms, signs, and abnormal clinical and laboratory findings, not elsewhere classified				
Cough	R05x			
Abnormalities of breathing	R06x			
Other symptoms of the circulatory/respiratory system	R09x			
Malaise/fatigue	R53x			
Abnormal findings in specimens from respiratory organs and thorax	R84x			
Abnormal findings on diagnostic imaging of lung	R91x			