

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

<u>Request Description</u>	<p>FDA requested use of Modular Program #3 to analyze diagnoses of acute myocardial infarction (AMI), stroke, intracranial hemorrhage (ICH), and pulmonary embolism (PE) among omalizumab or montelukast users. In addition, these members must have been diagnosed with asthma and exposed to inhaled corticosteroids (ICS) only (and excluding long-acting beta agonists (LABA) use) or ICS/LABA products (as combinations or concomitantly as separate products) prior to the omalizumab and montelukast exposures. This required one run of MP3. The time window for the request was June 23, 2003 to May 31, 2013. The package was distributed to 18 Data Partners on June 5, 2014. Please see the Specifications tab for more details on each scenario.</p>
<u>Request ID</u>	<p>to09y05_mpr_wp35_v01 - report 1 of 1</p>
<u>Specifications</u>	<p>Program parameter inputs and scenarios</p>
<u>Glossary</u>	<p>List of Terms found in this Report and their Definitions</p>
<u>Table 1</u>	<p>Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Number of Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug Product, Pre-existing Drug Use Criteria. and Event.</p>
<u>Table 2</u>	<p>Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Number of Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug Product, Pre-existing Drug Use Criteria. Event. and Age Group.</p>
<u>Table 3</u>	<p>Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Number of Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug Product, Pre-existing Drug Use Criteria. Event. and Sex.</p>
<u>Table 4</u>	<p>Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Number of Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug Product, Pre-existing Drug Use Criteria. Event. and Year.</p>
<u>Appendix A</u>	<p>List of event diagnosis codes</p>
<u>Notes:</u>	<p>Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.</p>

to09y05_mpr_wp35_v01 specifications

FDA requested use of MP3 to analyze diagnoses of AMI, stroke, ICH, and PE among omalizumab or montelukast users. In addition, these members must have been diagnosed with asthma and exposed to ICS only or

Enrollment Gap 45 days
 Age Groups 12-17, 18-44, 45-64, 65+
 Query Period 6/23/2003 - 5/31/2013
 Coverage Requirement Medical and Drug Coverage
 Enrollment Requirement 183 days

Scenario	Drug/Exposure								Pre-Existing Condition					
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Episode Truncation by Incident Exposure	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ PDX
1	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
2	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
3	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omaliuzumab	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
4	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include	-183	0	Any
5	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include	-183	0	Any
6	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omaliuzumab	Asthma (493*) and ICS and LABA use (in combination or separately)	Include	-183	0	Any
7	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
8	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
9	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omaliuzumab	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include	-183	0	Any
10	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include	-183	0	Any

11	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
12	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omalizumab	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
13	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
14	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
15	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omalizumab	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
16	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
17	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
18	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omalizumab	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
19	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
20	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
21	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omalizumab	Asthma (493*) and ICS only use and LABA use (alone or combos)	Include Include Exclude	-183 -90 -90	0 0 0	Any
22	Omaliuzumab NDC codes	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
23	Omaliuzumab procedure code (HCPCS J2357)	Omaliuzumab NDCs/HCPCS and montelukast	183	01	35	35	1	1	montelukast only	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any
24	Montelukast	Omaliuzumab NDCs/HCPCS and montelukast	183	01	14	14	1	1	any omalizumab	Asthma (493*) and ICS and LABA use (in combination or separately)	Include Include	-183 -90	0 0	Any

ICS and LABA use

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"
 ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight
 HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight
 CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Glossary of Terms in Modular Program 3*

- Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt"
- Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
- Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). Along with the Principal Diagnosis Indicator, forms the Caresetting/PDX parameter.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the
- Cohort Definition (drug/exposure)**- Indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment episodes during the query period until an event occurs
- Days Supplied** - number of days supplied for all dispensings in qualifying treatment episodes.
- Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.23.
- Eligible Members** - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
- Enrollment Gap** - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled"
- Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same
- Event De-duplication** - specifies how events are counted by the MP algorithm. '0' counts all occurrences of an event group code of interest. '1' de-duplicates occurrences of the same event code on the same day (i.e., de-duplicates at the exact match code level), '2' de-duplicates occurrences of the same event group code on the same day (e.g., de-duplicates at the GROUP level).
- Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode.
- Lookback Period (pre-existing condition)** - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).
- Member-Years** - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout
- Minimum Days Supplied** - specifies a minimum number of days in length of the days supplied for the episode to be considered
- Minimum Episode Duration** - specifies a minimum number of days in length of the episode for it to be considered
- New Episodes** - new treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive dispensings
- New Episodes with Events** - number of unique episodes during which at least one incident event occurs. Each episode may only be counted
- New Users** - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- Number of Events** - total number of incident events. An individual or a treatment episode can have more than one incident event provided that the incident event meets the event incidence criteria.
- Query Period** - period in which the modular program looks for exposures and outcomes of interest.
- Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.
- Washout Period (drug/exposure)**** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
- Washout Period (event/outcome)**** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1. Summary of Incident Drug use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Drug Use, and Event

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Omalizumab (NDC)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI	130	130	607	18,481	2,225	57.1	0	0	142.16	4.67	30.45	0.00
ICH	130	130	607	18,481	2,225	57.1	0	0	142.16	4.67	30.45	0.00
PE	130	130	607	18,481	2,225	57.1	0	0	142.16	4.67	30.45	0.00
Stroke	130	130	607	18,481	2,225	57.1	0	0	142.16	4.67	30.45	0.00
<i>Pre-existing ICS and LABA use</i>												
AMI	958	958	4,859	142,748	20,252	437.9	3	3	149.01	5.07	29.38	68.51
ICH	958	958	4,859	142,748	20,252	438.2	0	0	149.01	5.07	29.38	0.00
PE	958	958	4,859	142,748	20,252	438.1	1	6	149.01	5.07	29.38	22.83
Stroke	958	958	4,859	142,748	20,252	437.8	2	2	149.01	5.07	29.38	45.68
Omalizumab (HCPCS)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI	144	144	877	877	877	54.7	0	0	6.09	6.09	1.00	0.00
ICH	144	144	877	877	877	54.7	0	0	6.09	6.09	1.00	0.00
PE	144	144	877	877	877	53.5	2	3	6.09	6.09	1.00	374.15
Stroke	144	144	877	877	877	54.7	0	0	6.09	6.09	1.00	0.00
<i>Pre-existing ICS and LABA use</i>												
AMI	910	910	5,443	5,443	5,443	334.3	2	2	5.98	5.98	1.00	59.83
ICH	911	911	5,449	5,449	5,449	335.8	0	0	5.98	5.98	1.00	0.00
PE	910	910	5,448	5,448	5,448	335.4	4	7	5.99	5.99	1.00	119.26
Stroke	910	910	5,448	5,448	5,448	335.7	0	0	5.99	5.99	1.00	0.00
Montelukast												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI	83,405	83,405	225,097	9,268,360	9,396,489	28,937.0	64	76	111.12	2.70	41.17	22.12
ICH	83,442	83,442	225,168	9,271,395	9,399,524	28,974.5	29	43	111.11	2.70	41.18	10.01
PE	83,379	83,379	224,970	9,263,990	9,392,119	28,880.6	150	201	111.11	2.70	41.18	51.94
Stroke	83,419	83,419	225,091	9,268,997	9,397,086	28,939.6	77	102	111.11	2.70	41.18	26.61
<i>Pre-existing ICS and LABA use</i>												
AMI	177,327	177,327	545,529	20,637,552	21,137,936	64,230.8	206	226	116.38	3.08	37.83	32.07
ICH	177,444	177,444	546,010	20,654,350	21,154,859	64,358.0	91	146	116.40	3.08	37.83	14.14
PE	177,178	177,178	544,839	20,614,902	21,115,470	64,014.0	550	872	116.35	3.08	37.84	85.92
Stroke	177,363	177,363	545,646	20,640,859	21,141,376	64,216.0	297	447	116.38	3.08	37.83	46.25

Table 2. Summary of Incident Drug use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Drug Use, Event, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Omalizumab (NDC)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI												
12 to 17 Years	19	19	71	2,557	353	7.8	0	0	134.58	3.74	36.01	0.00
18 to 44 Years	55	55	232	6,900	926	21.6	0	0	125.45	4.22	29.74	0.00
45 to 64 Years	47	47	250	7,493	685	23.1	0	0	159.43	5.32	29.97	0.00
65+ Years	9	9	54	1,531	260	4.6	0	0	170.11	6.00	28.35	0.00
ICH												
12 to 17 Years	19	19	71	2,557	353	7.8	0	0	134.58	3.74	36.01	0.00
18 to 44 Years	55	55	232	6,900	926	21.6	0	0	125.45	4.22	29.74	0.00
45 to 64 Years	47	47	250	7,493	685	23.1	0	0	159.43	5.32	29.97	0.00
65+ Years	9	9	54	1,531	260	4.6	0	0	170.11	6.00	28.35	0.00
PE												
12 to 17 Years	19	19	71	2,557	353	7.8	0	0	134.58	3.74	36.01	0.00
18 to 44 Years	55	55	232	6,900	926	21.6	0	0	125.45	4.22	29.74	0.00
45 to 64 Years	47	47	250	7,493	685	23.1	0	0	159.43	5.32	29.97	0.00
65+ Years	9	9	54	1,531	260	4.6	0	0	170.11	6.00	28.35	0.00
Stroke												
12 to 17 Years	19	19	71	2,557	353	7.8	0	0	134.58	3.74	36.01	0.00
18 to 44 Years	55	55	232	6,900	926	21.6	0	0	125.45	4.22	29.74	0.00
45 to 64 Years	47	47	250	7,493	685	23.1	0	0	159.43	5.32	29.97	0.00
65+ Years	9	9	54	1,531	260	4.6	0	0	170.11	6.00	28.35	0.00
<i>Pre-existing ICS and LABA use</i>												
AMI												
12 to 17 Years	62	62	245	7,054	1,057	21.8	0	0	113.77	3.95	28.79	0.00
18 to 44 Years	358	358	1,744	51,525	8,591	157.7	1	1	143.92	4.87	29.54	63.42
45 to 64 Years	474	474	2,460	73,078	9,144	224.4	2	2	154.17	5.19	29.71	89.15
65+ Years	64	64	410	11,091	1,461	34.1	0	0	173.30	6.41	27.05	0.00
ICH												
12 to 17 Years	62	62	245	7,054	1,057	21.8	0	0	113.77	3.95	28.79	0.00
18 to 44 Years	358	358	1,744	51,525	8,591	157.8	0	0	143.92	4.87	29.54	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
45 to 64 Years	474	474	2,460	73,078	9,144	224.5	0	0	154.17	5.19	29.71	0.00
65+ Years	64	64	410	11,091	1,461	34.1	0	0	173.30	6.41	27.05	0.00
PE												
12 to 17 Years	62	62	245	7,054	1,057	21.8	0	0	113.77	3.95	28.79	0.00
18 to 44 Years	358	358	1,744	51,525	8,591	157.8	0	0	143.92	4.87	29.54	0.00
45 to 64 Years	474	474	2,460	73,078	9,144	224.5	0	0	154.17	5.19	29.71	0.00
65+ Years	64	64	410	11,091	1,461	34.0	1	6	173.30	6.41	27.05	294.01
Stroke												
12 to 17 Years	62	62	245	7,054	1,057	21.8	0	0	113.77	3.95	28.79	0.00
18 to 44 Years	358	358	1,744	51,525	8,591	157.8	0	0	143.92	4.87	29.54	0.00
45 to 64 Years	474	474	2,460	73,078	9,144	224.2	2	2	154.17	5.19	29.71	89.22
65+ Years	64	64	410	11,091	1,461	34.1	0	0	173.30	6.41	27.05	0.00

Omalizumab (HCPCS)

Pre-existing ICS only use (exclude episodes with prior LABA use)

AMI

12 to 17 Years	11	11	47	47	47	3.4	0	0	4.27	4.27	1.00	0.00
18 to 44 Years	53	53	233	233	233	16.0	0	0	4.40	4.40	1.00	0.00
45 to 64 Years	59	59	359	359	359	22.4	0	0	6.08	6.08	1.00	0.00
65+ Years	21	21	238	238	238	12.9	0	0	11.33	11.33	1.00	0.00

ICH

12 to 17 Years	11	11	47	47	47	3.4	0	0	4.27	4.27	1.00	0.00
18 to 44 Years	53	53	233	233	233	16.0	0	0	4.40	4.40	1.00	0.00
45 to 64 Years	59	59	359	359	359	22.4	0	0	6.08	6.08	1.00	0.00
65+ Years	21	21	238	238	238	12.9	0	0	11.33	11.33	1.00	0.00

PE

12 to 17 Years	11	11	47	47	47	3.4	0	0	4.27	4.27	1.00	0.00
18 to 44 Years	53	53	233	233	233	16.0	0	0	4.40	4.40	1.00	0.00
45 to 64 Years	59	59	359	359	359	22.1	1	1	6.08	6.08	1.00	452.55
65+ Years	21	21	238	238	238	12.0	1	2	11.33	11.33	1.00	836.39

Stroke

12 to 17 Years	11	11	47	47	47	3.4	0	0	4.27	4.27	1.00	0.00
18 to 44 Years	53	53	233	233	233	16.0	0	0	4.40	4.40	1.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
45 to 64 Years	59	59	359	359	359	22.4	0	0	6.08	6.08	1.00	0.00
65+ Years	21	21	238	238	238	12.9	0	0	11.33	11.33	1.00	0.00
Pre-existing ICS and LABA use												
AMI												
12 to 17 Years	51	51	157	157	157	11.0	0	0	3.08	3.08	1.00	0.00
18 to 44 Years	286	286	1,267	1,267	1,267	85.4	0	0	4.43	4.43	1.00	0.00
45 to 64 Years	454	454	2,837	2,837	2,837	175.1	1	1	6.25	6.25	1.00	57.12
65+ Years	119	119	1,182	1,182	1,182	62.7	1	1	9.93	9.93	1.00	159.46
ICH												
12 to 17 Years	51	51	157	157	157	11.0	0	0	3.08	3.08	1.00	0.00
18 to 44 Years	286	286	1,267	1,267	1,267	85.4	0	0	4.43	4.43	1.00	0.00
45 to 64 Years	454	454	2,837	2,837	2,837	176.2	0	0	6.25	6.25	1.00	0.00
65+ Years	120	120	1,188	1,188	1,188	63.1	0	0	9.90	9.90	1.00	0.00
PE												
12 to 17 Years	51	51	157	157	157	11.0	0	0	3.08	3.08	1.00	0.00
18 to 44 Years	286	286	1,267	1,267	1,267	85.4	0	0	4.43	4.43	1.00	0.00
45 to 64 Years	453	453	2,836	2,836	2,836	176.0	2	2	6.26	6.26	1.00	113.62
65+ Years	120	120	1,188	1,188	1,188	62.9	2	5	9.90	9.90	1.00	317.95
Stroke												
12 to 17 Years	51	51	157	157	157	11.0	0	0	3.08	3.08	1.00	0.00
18 to 44 Years	286	286	1,267	1,267	1,267	85.4	0	0	4.43	4.43	1.00	0.00
45 to 64 Years	453	453	2,836	2,836	2,836	176.1	0	0	6.26	6.26	1.00	0.00
65+ Years	120	120	1,188	1,188	1,188	63.1	0	0	9.90	9.90	1.00	0.00

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Pre-existing ICS only use (exclude episodes with prior LABA use)												
AMI												
12 to 17 Years	20,293	20,293	36,528	1,392,688	1,403,318	4,659.5	0	0	68.63	1.80	38.13	0.00
18 to 44 Years	30,188	30,188	70,401	2,682,631	2,785,966	8,639.0	1	1	88.86	2.33	38.11	1.16
45 to 64 Years	25,097	25,097	87,362	3,757,741	3,769,382	11,401.9	20	23	149.73	3.48	43.01	17.54
65+ Years	7,827	7,827	30,806	1,435,300	1,437,823	4,236.6	43	52	183.38	3.94	46.59	101.50
ICH												
12 to 17 Years	20,293	20,293	36,528	1,392,688	1,403,318	4,658.8	2	2	68.63	1.80	38.13	4.29
18 to 44 Years	30,192	30,192	70,408	2,682,826	2,786,161	8,639.8	2	2	88.86	2.33	38.10	2.31

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
45 to 64 Years	25,114	25,114	87,401	3,758,985	3,770,626	11,413.5	10	14	149.68	3.48	43.01	8.76
65+ Years	7,843	7,843	30,831	1,436,896	1,439,419	4,262.5	15	25	183.21	3.93	46.61	35.19
PE												
12 to 17 Years	20,286	20,286	36,517	1,392,223	1,402,853	4,657.5	3	3	68.63	1.80	38.13	6.44
18 to 44 Years	30,176	30,176	70,379	2,681,596	2,784,931	8,623.5	22	23	88.87	2.33	38.10	25.51
45 to 64 Years	25,086	25,086	87,292	3,754,727	3,766,368	11,366.3	67	86	149.67	3.48	43.01	58.95
65+ Years	7,831	7,831	30,782	1,435,444	1,437,967	4,233.3	58	89	183.30	3.93	46.63	137.01
Stroke												
12 to 17 Years	20,292	20,292	36,524	1,392,585	1,403,215	4,656.8	1	1	68.63	1.80	38.13	2.15
18 to 44 Years	30,193	30,193	70,409	2,682,856	2,786,191	8,637.8	9	9	88.86	2.33	38.10	10.42
45 to 64 Years	25,106	25,106	87,376	3,758,315	3,769,916	11,404.3	30	38	149.70	3.48	43.01	26.31
65+ Years	7,828	7,828	30,782	1,435,241	1,437,764	4,240.7	37	54	183.35	3.93	46.63	87.25
Pre-existing ICS and LABA use												
AMI												
12 to 17 Years	18,322	18,322	35,006	1,220,675	1,317,722	4,121.5	0	0	66.62	1.91	34.87	0.00
18 to 44 Years	66,092	66,092	162,045	5,703,857	5,834,808	18,496.4	6	6	86.30	2.45	35.20	3.24
45 to 64 Years	70,303	70,303	259,075	10,016,663	10,164,976	30,573.0	104	114	142.48	3.69	38.66	34.02
65+ Years	22,610	22,610	89,403	3,696,357	3,820,430	11,039.9	96	106	163.48	3.95	41.34	86.96
ICH												
12 to 17 Years	18,322	18,322	35,006	1,220,675	1,317,722	4,121.5	0	0	66.62	1.91	34.87	0.00
18 to 44 Years	66,096	66,096	162,077	5,704,821	5,835,772	18,498.9	11	12	86.31	2.45	35.20	5.95
45 to 64 Years	70,354	70,354	259,239	10,022,820	10,171,133	30,629.6	36	70	142.46	3.68	38.66	11.75
65+ Years	22,672	22,672	89,688	3,706,034	3,830,232	11,108.1	44	64	163.46	3.96	41.32	39.61
PE												
12 to 17 Years	18,321	18,321	35,005	1,220,645	1,317,692	4,120.6	1	2	66.63	1.91	34.87	2.43
18 to 44 Years	66,043	66,043	161,849	5,697,061	5,828,012	18,452.8	70	107	86.26	2.45	35.20	37.93
45 to 64 Years	70,234	70,234	258,708	10,004,845	10,153,188	30,468.2	236	328	142.45	3.68	38.67	77.46
65+ Years	22,580	22,580	89,277	3,692,351	3,816,578	10,972.4	243	435	163.52	3.95	41.36	221.46
Stroke												
12 to 17 Years	18,322	18,322	35,006	1,220,675	1,317,722	4,121.4	1	1	66.62	1.91	34.87	2.43
18 to 44 Years	66,091	66,091	162,047	5,703,917	5,834,868	18,494.4	20	21	86.30	2.45	35.20	10.81
45 to 64 Years	70,330	70,330	259,180	10,020,985	10,169,298	30,591.6	97	134	142.49	3.69	38.66	31.71
65+ Years	22,620	22,620	89,413	3,695,282	3,819,488	11,008.6	179	291	163.36	3.95	41.33	162.60

Table 3. Summary of Incident Drug use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Drug Use, Event, and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Omalizumab (NDC)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI												
Female	76	76	312	9,560	1,101	30.1	0	0	125.79	4.11	30.64	0.00
Male	54	54	295	8,921	1,124	27.0	0	0	165.20	5.46	30.24	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
ICH												
Female	76	76	312	9,560	1,101	30.1	0	0	125.79	4.11	30.64	0.00
Male	54	54	295	8,921	1,124	27.0	0	0	165.20	5.46	30.24	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
PE												
Female	76	76	312	9,560	1,101	30.1	0	0	125.79	4.11	30.64	0.00
Male	54	54	295	8,921	1,124	27.0	0	0	165.20	5.46	30.24	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
Stroke												
Female	76	76	312	9,560	1,101	30.1	0	0	125.79	4.11	30.64	0.00
Male	54	54	295	8,921	1,124	27.0	0	0	165.20	5.46	30.24	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
<i>Pre-existing ICS and LABA use</i>												
AMI												
Female	580	580	2,852	84,740	12,362	260.2	0	0	146.10	4.92	29.71	0.00
Male	378	378	2,007	58,008	7,890	177.7	3	3	153.46	5.31	28.90	168.85
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
ICH												
Female	580	580	2,852	84,740	12,362	260.2	0	0	146.10	4.92	29.71	0.00
Male	378	378	2,007	58,008	7,890	178.0	0	0	153.46	5.31	28.90	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
PE												
Female	580	580	2,852	84,740	12,362	260.2	0	0	146.10	4.92	29.71	0.00
Male	378	378	2,007	58,008	7,890	177.9	1	6	153.46	5.31	28.90	56.21
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Stroke												
Female	580	580	2,852	84,740	12,362	260.2	0	0	146.10	4.92	29.71	0.00
Male	378	378	2,007	58,008	7,890	177.6	2	2	153.46	5.31	28.90	112.60
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
Omalizumab (HCPCS)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI												
Female	102	102	514	514	514	33.6	0	0	5.04	5.04	1.00	0.00
Male	42	42	363	363	363	21.1	0	0	8.64	8.64	1.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
ICH												
Female	102	102	514	514	514	33.6	0	0	5.04	5.04	1.00	0.00
Male	42	42	363	363	363	21.1	0	0	8.64	8.64	1.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
PE												
Female	102	102	514	514	514	33.3	1	1	5.04	5.04	1.00	300.39
Male	42	42	363	363	363	20.2	1	2	8.64	8.64	1.00	495.93
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
Stroke												
Female	102	102	514	514	514	33.6	0	0	5.04	5.04	1.00	0.00
Male	42	42	363	363	363	21.1	0	0	8.64	8.64	1.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
<i>Pre-existing ICS and LABA use</i>												
AMI												
Female	534	534	3,357	3,357	3,357	204.0	1	1	6.29	6.29	1.00	49.02
Male	376	376	2,086	2,086	2,086	130.3	1	1	5.55	5.55	1.00	76.76
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
ICH												
Female	535	535	3,363	3,363	3,363	204.3	0	0	6.29	6.29	1.00	0.00
Male	376	376	2,086	2,086	2,086	131.4	0	0	5.55	5.55	1.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
PE												
Female	535	535	3,363	3,363	3,363	204.1	3	4	6.29	6.29	1.00	146.96

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Male	375	375	2,085	2,085	2,085	131.3	1	3	5.56	5.56	1.00	76.19
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---
Stroke												
Female	535	535	3,363	3,363	3,363	204.3	0	0	6.29	6.29	1.00	0.00
Male	375	375	2,085	2,085	2,085	131.3	0	0	5.56	5.56	1.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	---	---	---	---

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Pre-existing ICS only use (exclude episodes with prior LABA use)

AMI

Female	53,683	53,683	151,977	6,263,579	6,348,084	19,462.8	40	44	116.68	2.83	41.21	20.55
Male	29,706	29,706	73,082	3,003,461	3,047,085	9,469.9	24	32	101.11	2.46	41.10	25.34
Unknown	16	16	38	1,320	1,320	4.3	0	0	82.50	2.38	34.74	0.00

ICH

Female	53,699	53,699	152,029	6,265,771	6,350,276	19,484.4	17	27	116.68	2.83	41.21	8.72
Male	29,727	29,727	73,101	3,004,304	3,047,928	9,485.7	12	16	101.06	2.46	41.10	12.65
Unknown	16	16	38	1,320	1,320	4.3	0	0	82.50	2.38	34.74	0.00

PE

Female	53,649	53,649	151,841	6,258,334	6,342,839	19,402.7	113	156	116.65	2.83	41.22	58.24
Male	29,714	29,714	73,091	3,004,336	3,047,960	9,473.6	37	45	101.11	2.46	41.10	39.06
Unknown	16	16	38	1,320	1,320	4.3	0	0	82.50	2.38	34.74	0.00

Stroke

Female	53,682	53,682	151,971	6,263,746	6,348,211	19,457.2	57	79	116.68	2.83	41.22	29.30
Male	29,721	29,721	73,082	3,003,931	3,047,555	9,478.1	20	23	101.07	2.46	41.10	21.10
Unknown	16	16	38	1,320	1,320	4.3	0	0	82.50	2.38	34.74	0.00

Pre-existing ICS and LABA use

AMI

Female	114,901	114,901	362,837	13,754,492	14,118,812	42,685.0	128	144	119.71	3.16	37.91	29.99
Male	62,363	62,363	182,442	6,875,168	7,011,174	21,521.1	78	82	110.24	2.93	37.68	36.24
Unknown	63	63	250	7,892	7,950	24.7	0	0	125.27	3.97	31.57	0.00

ICH

Female	114,968	114,968	363,128	13,764,174	14,128,619	42,754.8	60	98	119.72	3.16	37.90	14.03
Male	62,413	62,413	182,632	6,882,284	7,018,290	21,578.5	31	48	110.27	2.93	37.68	14.37
Unknown	63	63	250	7,892	7,950	24.7	0	0	125.27	3.97	31.57	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
PE												
Female	114,789	114,789	362,332	13,737,003	14,101,478	42,518.5	366	616	119.67	3.16	37.91	86.08
Male	62,326	62,326	182,257	6,870,007	7,006,042	21,470.8	184	256	110.23	2.92	37.69	85.70
Unknown	63	63	250	7,892	7,950	24.7	0	0	125.27	3.97	31.57	0.00
Stroke												
Female	114,919	114,919	362,883	13,755,389	14,119,834	42,654.9	207	325	119.70	3.16	37.91	48.53
Male	62,381	62,381	182,513	6,877,578	7,013,592	21,536.4	90	122	110.25	2.93	37.68	41.79
Unknown	63	63	250	7,892	7,950	24.7	0	0	125.27	3.97	31.57	0.00

Table 4. Summary of Incident Drug use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Drug Use, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
Omalizumab (NDC)												
<i>Pre-existing ICS only use (exclude episodes with prior LABA use)</i>												
AMI												
2003	4	4	73	2,031	149	5.9	0	0	507.75	18.25	27.82	0.00
2004	2	2	29	780	74	2.3	0	0	390.00	14.50	26.90	0.00
2005	0	0	0	0	0	0.0	0	0	---	---	---	---
2006	9	9	48	1,598	299	4.8	0	0	177.56	5.33	33.29	0.00
2007	15	15	33	1,352	150	4.3	0	0	90.13	2.20	40.97	0.00
2008	25	25	122	3,812	401	11.9	0	0	152.48	4.88	31.25	0.00
2009	20	20	64	1,995	217	6.2	0	0	99.75	3.20	31.17	0.00
2010	15	15	44	1,283	144	4.1	0	0	85.53	2.93	29.16	0.00
2011	20	20	96	2,921	462	9.3	0	0	146.05	4.80	30.43	0.00
2012	14	14	73	2,004	226	6.1	0	0	143.14	5.21	27.45	0.00
2013	6	6	25	705	104	2.2	0	0	117.50	4.17	28.20	0.00
ICH												
2003	4	4	73	2,031	149	5.9	0	0	507.75	18.25	27.82	0.00
2004	2	2	29	780	74	2.3	0	0	390.00	14.50	26.90	0.00
2005	0	0	0	0	0	0.0	0	0	---	---	---	---
2006	9	9	48	1,598	299	4.8	0	0	177.56	5.33	33.29	0.00
2007	15	15	33	1,352	150	4.3	0	0	90.13	2.20	40.97	0.00
2008	25	25	122	3,812	401	11.9	0	0	152.48	4.88	31.25	0.00
2009	20	20	64	1,995	217	6.2	0	0	99.75	3.20	31.17	0.00
2010	15	15	44	1,283	144	4.1	0	0	85.53	2.93	29.16	0.00
2011	20	20	96	2,921	462	9.3	0	0	146.05	4.80	30.43	0.00
2012	14	14	73	2,004	226	6.1	0	0	143.14	5.21	27.45	0.00
2013	6	6	25	705	104	2.2	0	0	117.50	4.17	28.20	0.00
PE												
2003	4	4	73	2,031	149	5.9	0	0	507.75	18.25	27.82	0.00
2004	2	2	29	780	74	2.3	0	0	390.00	14.50	26.90	0.00
2005	0	0	0	0	0	0.0	0	0	---	---	---	---

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2006	9	9	48	1,598	299	4.8	0	0	177.56	5.33	33.29	0.00
2007	15	15	33	1,352	150	4.3	0	0	90.13	2.20	40.97	0.00
2008	25	25	122	3,812	401	11.9	0	0	152.48	4.88	31.25	0.00
2009	20	20	64	1,995	217	6.2	0	0	99.75	3.20	31.17	0.00
2010	15	15	44	1,283	144	4.1	0	0	85.53	2.93	29.16	0.00
2011	20	20	96	2,921	462	9.3	0	0	146.05	4.80	30.43	0.00
2012	14	14	73	2,004	226	6.1	0	0	143.14	5.21	27.45	0.00
2013	6	6	25	705	104	2.2	0	0	117.50	4.17	28.20	0.00
Stroke												
2003	4	4	73	2,031	149	5.9	0	0	507.75	18.25	27.82	0.00
2004	2	2	29	780	74	2.3	0	0	390.00	14.50	26.90	0.00
2005	0	0	0	0	0	0.0	0	0	---	---	---	---
2006	9	9	48	1,598	299	4.8	0	0	177.56	5.33	33.29	0.00
2007	15	15	33	1,352	150	4.3	0	0	90.13	2.20	40.97	0.00
2008	25	25	122	3,812	401	11.9	0	0	152.48	4.88	31.25	0.00
2009	20	20	64	1,995	217	6.2	0	0	99.75	3.20	31.17	0.00
2010	15	15	44	1,283	144	4.1	0	0	85.53	2.93	29.16	0.00
2011	20	20	96	2,921	462	9.3	0	0	146.05	4.80	30.43	0.00
2012	14	14	73	2,004	226	6.1	0	0	143.14	5.21	27.45	0.00
2013	6	6	25	705	104	2.2	0	0	117.50	4.17	28.20	0.00
Pre-existing ICS and LABA use												
AMI												
2003	17	17	103	2,870	286	8.5	0	0	168.82	6.06	27.86	0.00
2004	28	28	381	10,146	3,286	29.5	0	0	362.36	13.61	26.63	0.00
2005	25	25	266	7,374	997	21.3	0	0	294.96	10.64	27.72	0.00
2006	54	54	285	9,888	1,280	29.2	0	0	183.11	5.28	34.69	0.00
2007	70	70	354	13,372	1,746	40.1	0	0	191.03	5.06	37.77	0.00
2008	115	115	679	19,635	2,207	59.5	3	3	170.74	5.90	28.92	504.42
2009	166	166	698	19,973	2,861	63.2	0	0	120.32	4.20	28.61	0.00
2010	139	139	564	15,811	2,003	50.0	0	0	113.75	4.06	28.03	0.00
2011	163	163	808	22,456	2,848	70.0	0	0	137.77	4.96	27.79	0.00
2012	145	145	613	17,950	2,389	56.2	0	0	123.79	4.23	29.28	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2013	36	36	108	3,273	348	10.4	0	0	90.92	3.00	30.31	0.00
ICH												
2003	17	17	103	2,870	286	8.5	0	0	168.82	6.06	27.86	0.00
2004	28	28	381	10,146	3,286	29.5	0	0	362.36	13.61	26.63	0.00
2005	25	25	266	7,374	997	21.3	0	0	294.96	10.64	27.72	0.00
2006	54	54	285	9,888	1,280	29.2	0	0	183.11	5.28	34.69	0.00
2007	70	70	354	13,372	1,746	40.1	0	0	191.03	5.06	37.77	0.00
2008	115	115	679	19,635	2,207	59.8	0	0	170.74	5.90	28.92	0.00
2009	166	166	698	19,973	2,861	63.2	0	0	120.32	4.20	28.61	0.00
2010	139	139	564	15,811	2,003	50.0	0	0	113.75	4.06	28.03	0.00
2011	163	163	808	22,456	2,848	70.0	0	0	137.77	4.96	27.79	0.00
2012	145	145	613	17,950	2,389	56.2	0	0	123.79	4.23	29.28	0.00
2013	36	36	108	3,273	348	10.4	0	0	90.92	3.00	30.31	0.00
PE												
2003	17	17	103	2,870	286	8.5	0	0	168.82	6.06	27.86	0.00
2004	28	28	381	10,146	3,286	29.5	0	0	362.36	13.61	26.63	0.00
2005	25	25	266	7,374	997	21.3	0	0	294.96	10.64	27.72	0.00
2006	54	54	285	9,888	1,280	29.2	0	0	183.11	5.28	34.69	0.00
2007	70	70	354	13,372	1,746	40.1	0	0	191.03	5.06	37.77	0.00
2008	115	115	679	19,635	2,207	59.8	0	0	170.74	5.90	28.92	0.00
2009	166	166	698	19,973	2,861	63.2	0	0	120.32	4.20	28.61	0.00
2010	139	139	564	15,811	2,003	50.0	0	0	113.75	4.06	28.03	0.00
2011	163	163	808	22,456	2,848	70.0	0	0	137.77	4.96	27.79	0.00
2012	145	145	613	17,950	2,389	56.1	1	6	123.79	4.23	29.28	178.25
2013	36	36	108	3,273	348	10.4	0	0	90.92	3.00	30.31	0.00
Stroke												
2003	17	17	103	2,870	286	8.5	0	0	168.82	6.06	27.86	0.00
2004	28	28	381	10,146	3,286	29.5	0	0	362.36	13.61	26.63	0.00
2005	25	25	266	7,374	997	21.3	0	0	294.96	10.64	27.72	0.00
2006	54	54	285	9,888	1,280	29.2	0	0	183.11	5.28	34.69	0.00
2007	70	70	354	13,372	1,746	40.1	0	0	191.03	5.06	37.77	0.00
2008	115	115	679	19,635	2,207	59.8	0	0	170.74	5.90	28.92	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2009	166	166	698	19,973	2,861	63.1	1	1	120.32	4.20	28.61	158.40
2010	139	139	564	15,811	2,003	50.0	0	0	113.75	4.06	28.03	0.00
2011	163	163	808	22,456	2,848	69.7	1	1	137.77	4.96	27.79	143.49
2012	145	145	613	17,950	2,389	56.2	0	0	123.79	4.23	29.28	0.00
2013	36	36	108	3,273	348	10.4	0	0	90.92	3.00	30.31	0.00

Omalizumab (HCPCS)

Pre-existing ICS only use (exclude episodes with prior LABA use)

AMI

2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	1	1	4	4	4	0.2	0	0	4.00	4.00	1.00	0.00
2006	4	4	6	6	6	0.5	0	0	1.50	1.50	1.00	0.00
2007	14	14	30	30	30	2.6	0	0	2.14	2.14	1.00	0.00
2008	17	17	219	219	219	12.2	0	0	12.88	12.88	1.00	0.00
2009	19	19	212	212	212	11.3	0	0	11.16	11.16	1.00	0.00
2010	22	22	118	118	118	8.6	0	0	5.36	5.36	1.00	0.00
2011	29	29	112	112	112	8.9	0	0	3.86	3.86	1.00	0.00
2012	25	25	128	128	128	7.5	0	0	5.12	5.12	1.00	0.00
2013	13	13	48	48	48	3.0	0	0	3.69	3.69	1.00	0.00

ICH

2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	1	1	4	4	4	0.2	0	0	4.00	4.00	1.00	0.00
2006	4	4	6	6	6	0.5	0	0	1.50	1.50	1.00	0.00
2007	14	14	30	30	30	2.6	0	0	2.14	2.14	1.00	0.00
2008	17	17	219	219	219	12.2	0	0	12.88	12.88	1.00	0.00
2009	19	19	212	212	212	11.3	0	0	11.16	11.16	1.00	0.00
2010	22	22	118	118	118	8.6	0	0	5.36	5.36	1.00	0.00
2011	29	29	112	112	112	8.9	0	0	3.86	3.86	1.00	0.00
2012	25	25	128	128	128	7.5	0	0	5.12	5.12	1.00	0.00
2013	13	13	48	48	48	3.0	0	0	3.69	3.69	1.00	0.00

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
PE												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	1	1	4	4	4	0.2	0	0	4.00	4.00	1.00	0.00
2006	4	4	6	6	6	0.5	0	0	1.50	1.50	1.00	0.00
2007	14	14	30	30	30	2.6	0	0	2.14	2.14	1.00	0.00
2008	17	17	219	219	219	12.2	0	0	12.88	12.88	1.00	0.00
2009	19	19	212	212	212	10.4	1	2	11.16	11.16	1.00	963.72
2010	22	22	118	118	118	8.6	0	0	5.36	5.36	1.00	0.00
2011	29	29	112	112	112	8.9	0	0	3.86	3.86	1.00	0.00
2012	25	25	128	128	128	7.2	1	1	5.12	5.12	1.00	1394.08
2013	13	13	48	48	48	3.0	0	0	3.69	3.69	1.00	0.00
Stroke												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	1	1	4	4	4	0.2	0	0	4.00	4.00	1.00	0.00
2006	4	4	6	6	6	0.5	0	0	1.50	1.50	1.00	0.00
2007	14	14	30	30	30	2.6	0	0	2.14	2.14	1.00	0.00
2008	17	17	219	219	219	12.2	0	0	12.88	12.88	1.00	0.00
2009	19	19	212	212	212	11.3	0	0	11.16	11.16	1.00	0.00
2010	22	22	118	118	118	8.6	0	0	5.36	5.36	1.00	0.00
2011	29	29	112	112	112	8.9	0	0	3.86	3.86	1.00	0.00
2012	25	25	128	128	128	7.5	0	0	5.12	5.12	1.00	0.00
2013	13	13	48	48	48	3.0	0	0	3.69	3.69	1.00	0.00
Pre-existing ICS and LABA use												
AMI												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	14	14	173	173	173	10.1	0	0	12.36	12.36	1.00	0.00
2006	29	29	266	266	266	15.2	0	0	9.17	9.17	1.00	0.00
2007	43	43	466	466	466	27.1	0	0	10.84	10.84	1.00	0.00
2008	122	122	612	612	612	41.2	0	0	5.02	5.02	1.00	0.00



	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2009	184	184	1,109	1,109	1,109	66.8	1	1	6.03	6.03	1.00	149.77
2010	185	185	1,093	1,093	1,093	69.3	0	0	5.91	5.91	1.00	0.00
2011	148	148	972	972	972	57.0	1	1	6.57	6.57	1.00	175.40
2012	138	138	577	577	577	37.1	0	0	4.18	4.18	1.00	0.00
2013	47	47	175	175	175	10.5	0	0	3.72	3.72	1.00	0.00
ICH												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	14	14	173	173	173	10.1	0	0	12.36	12.36	1.00	0.00
2006	29	29	266	266	266	15.2	0	0	9.17	9.17	1.00	0.00
2007	43	43	466	466	466	27.1	0	0	10.84	10.84	1.00	0.00
2008	122	122	612	612	612	41.2	0	0	5.02	5.02	1.00	0.00
2009	184	184	1,109	1,109	1,109	67.9	0	0	6.03	6.03	1.00	0.00
2010	185	185	1,093	1,093	1,093	69.3	0	0	5.91	5.91	1.00	0.00
2011	148	148	972	972	972	57.1	0	0	6.57	6.57	1.00	0.00
2012	139	139	583	583	583	37.3	0	0	4.19	4.19	1.00	0.00
2013	47	47	175	175	175	10.5	0	0	3.72	3.72	1.00	0.00
PE												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---
2005	14	14	173	173	173	10.1	0	0	12.36	12.36	1.00	0.00
2006	29	29	266	266	266	15.2	0	0	9.17	9.17	1.00	0.00
2007	43	43	466	466	466	27.1	0	0	10.84	10.84	1.00	0.00
2008	122	122	612	612	612	41.2	0	0	5.02	5.02	1.00	0.00
2009	184	184	1,109	1,109	1,109	67.9	0	0	6.03	6.03	1.00	0.00
2010	185	185	1,093	1,093	1,093	69.2	1	1	5.91	5.91	1.00	144.46
2011	148	148	972	972	972	56.9	2	3	6.57	6.57	1.00	351.20
2012	139	139	583	583	583	37.3	1	3	4.19	4.19	1.00	268.37
2013	46	46	174	174	174	10.4	0	0	3.78	3.78	1.00	0.00
Stroke												
2003	0	0	0	0	0	0.0	0	0	---	---	---	---
2004	0	0	0	0	0	0.0	0	0	---	---	---	---

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2005	14	14	173	173	173	10.1	0	0	12.36	12.36	1.00	0.00
2006	29	29	266	266	266	15.2	0	0	9.17	9.17	1.00	0.00
2007	43	43	466	466	466	27.1	0	0	10.84	10.84	1.00	0.00
2008	122	122	612	612	612	41.2	0	0	5.02	5.02	1.00	0.00
2009	184	184	1,109	1,109	1,109	67.9	0	0	6.03	6.03	1.00	0.00
2010	185	185	1,093	1,093	1,093	69.3	0	0	5.91	5.91	1.00	0.00
2011	148	148	972	972	972	57.1	0	0	6.57	6.57	1.00	0.00
2012	139	139	583	583	583	37.3	0	0	4.19	4.19	1.00	0.00
2013	46	46	174	174	174	10.4	0	0	3.78	3.78	1.00	0.00

Montelukast

Pre-existing ICS only use (exclude episodes with prior LABA use)

AMI

2003	1,576	1,576	6,888	282,878	344,501	851.2	4	4	179.49	4.37	41.07	46.99
2004	3,027	3,027	11,875	531,550	565,857	1,600.7	4	5	175.60	3.92	44.76	24.99
2005	3,075	3,075	9,470	477,628	482,627	1,439.3	3	6	155.33	3.08	50.44	20.84
2006	6,183	6,183	18,195	849,833	852,521	2,607.7	9	12	137.45	2.94	46.71	34.51
2007	8,131	8,131	23,896	1,042,489	1,046,298	3,218.7	8	8	128.21	2.94	43.63	24.85
2008	9,355	9,355	26,521	1,136,732	1,140,452	3,528.7	6	6	121.51	2.83	42.86	17.00
2009	12,007	12,007	33,442	1,314,487	1,317,072	4,120.8	12	16	109.48	2.79	39.31	29.12
2010	11,511	11,511	29,795	1,165,644	1,171,082	3,693.4	5	5	101.26	2.59	39.12	13.54
2011	10,865	10,865	26,776	1,045,644	1,049,134	3,328.9	3	3	96.24	2.46	39.05	9.01
2012	11,690	11,690	27,327	1,027,759	1,031,874	3,287.9	5	5	87.92	2.34	37.61	15.21
2013	5,985	5,985	10,912	393,716	395,072	1,259.6	5	6	65.78	1.82	36.08	39.69

ICH

2003	1,579	1,579	6,893	283,028	344,651	852.2	0	0	179.25	4.37	41.06	0.00
2004	3,027	3,027	11,875	531,550	565,857	1,601.5	2	3	175.60	3.92	44.76	12.49
2005	3,077	3,077	9,479	478,078	483,077	1,449.1	1	1	155.37	3.08	50.44	6.90
2006	6,189	6,189	18,202	850,141	852,829	2,608.1	6	9	137.36	2.94	46.71	23.01
2007	8,138	8,138	23,910	1,042,913	1,046,722	3,229.0	1	1	128.15	2.94	43.62	3.10
2008	9,362	9,362	26,558	1,138,518	1,142,238	3,536.0	6	7	121.61	2.84	42.87	16.97
2009	12,009	12,009	33,449	1,314,697	1,317,282	4,130.8	1	2	109.48	2.79	39.30	2.42
2010	11,512	11,512	29,796	1,165,744	1,171,182	3,692.2	5	9	101.26	2.59	39.12	13.54

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2011	10,867	10,867	26,750	1,044,594	1,048,084	3,325.2	3	6	96.13	2.46	39.05	9.02
2012	11,696	11,696	27,342	1,028,286	1,032,401	3,289.6	3	4	87.92	2.34	37.61	9.12
2013	5,986	5,986	10,914	393,846	395,202	1,260.7	1	1	65.79	1.82	36.09	7.93
PE												
2003	1,578	1,578	6,875	282,458	344,081	846.7	4	4	179.00	4.36	41.08	47.24
2004	3,025	3,025	11,829	529,030	563,337	1,590.4	8	9	174.89	3.91	44.72	50.30
2005	3,074	3,074	9,476	477,988	482,987	1,446.6	1	1	155.49	3.08	50.44	6.91
2006	6,184	6,184	18,192	849,841	852,529	2,606.4	15	20	137.43	2.94	46.72	57.55
2007	8,127	8,127	23,886	1,042,133	1,045,942	3,213.2	13	19	128.23	2.94	43.63	40.46
2008	9,357	9,357	26,527	1,137,518	1,141,238	3,517.6	19	20	121.57	2.83	42.88	54.01
2009	12,000	12,000	33,408	1,313,315	1,315,900	4,112.2	22	31	109.44	2.78	39.31	53.50
2010	11,501	11,501	29,780	1,165,326	1,170,764	3,680.0	23	43	101.32	2.59	39.13	62.50
2011	10,861	10,861	26,767	1,045,026	1,048,516	3,323.7	17	17	96.22	2.46	39.04	51.15
2012	11,685	11,685	27,318	1,027,506	1,031,621	3,283.6	21	29	87.93	2.34	37.61	63.95
2013	5,987	5,987	10,912	393,849	395,205	1,260.3	7	8	65.78	1.82	36.09	55.54
Stroke												
2003	1,579	1,579	6,893	283,028	344,651	851.4	2	2	179.25	4.37	41.06	23.49
2004	3,025	3,025	11,869	531,392	565,699	1,595.7	5	5	175.67	3.92	44.77	31.33
2005	3,076	3,076	9,473	477,898	482,897	1,447.1	3	5	155.36	3.08	50.45	20.73
2006	6,185	6,185	18,172	849,061	851,749	2,608.9	8	11	137.28	2.94	46.72	30.66
2007	8,137	8,137	23,909	1,042,883	1,046,692	3,222.3	8	10	128.17	2.94	43.62	24.83
2008	9,361	9,361	26,559	1,138,455	1,142,135	3,526.6	12	15	121.62	2.84	42.87	34.03
2009	12,008	12,008	33,448	1,314,667	1,317,252	4,129.1	8	13	109.48	2.79	39.30	19.37
2010	11,508	11,508	29,785	1,165,414	1,170,852	3,687.0	13	18	101.27	2.59	39.13	35.26
2011	10,863	10,863	26,749	1,044,674	1,048,164	3,324.4	9	11	96.17	2.46	39.05	27.07
2012	11,695	11,695	27,341	1,028,256	1,032,371	3,288.8	5	8	87.92	2.34	37.61	15.20
2013	5,982	5,982	10,893	393,269	394,625	1,258.3	4	4	65.74	1.82	36.10	31.79
Pre-existing ICS and LABA use												
AMI												
2003	3,230	3,230	14,836	538,845	631,573	1,636.6	1	1	166.83	4.59	36.32	6.11
2004	6,699	6,699	29,547	1,086,571	1,449,874	3,299.7	12	13	162.20	4.41	36.77	36.37
2005	5,400	5,400	20,000	837,433	842,265	2,539.3	7	7	155.08	3.70	41.87	27.57

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2006	9,570	9,570	35,883	1,464,151	1,470,603	4,464.4	13	16	152.99	3.75	40.80	29.12
2007	14,508	14,508	49,250	1,966,759	1,971,129	6,063.3	18	19	135.56	3.39	39.93	29.69
2008	22,810	22,810	69,344	2,643,987	2,650,262	8,268.5	21	22	115.91	3.04	38.13	25.40
2009	30,393	30,393	91,487	3,442,047	3,449,641	10,765.0	43	47	113.25	3.01	37.62	39.94
2010	26,935	26,935	79,289	2,967,728	2,972,304	9,307.9	29	30	110.18	2.94	37.43	31.16
2011	22,925	22,925	67,400	2,521,404	2,526,236	7,897.6	21	23	109.98	2.94	37.41	26.59
2012	23,489	23,489	64,569	2,332,276	2,335,964	7,336.8	27	31	99.29	2.75	36.12	36.80
2013	11,368	11,368	23,924	836,351	838,085	2,651.7	14	17	73.57	2.10	34.96	52.80
ICH												
2003	3,234	3,234	14,841	538,995	631,723	1,636.3	2	2	166.67	4.59	36.32	12.22
2004	6,699	6,699	29,555	1,086,811	1,450,114	3,304.4	3	3	162.23	4.41	36.77	9.08
2005	5,406	5,406	20,015	838,423	843,255	2,554.0	2	20	155.09	3.70	41.89	7.83
2006	9,574	9,574	35,896	1,464,640	1,471,092	4,470.4	3	6	152.98	3.75	40.80	6.71
2007	14,522	14,522	49,313	1,968,632	1,973,002	6,082.5	6	10	135.56	3.40	39.92	9.86
2008	22,830	22,830	69,409	2,646,126	2,652,526	8,276.0	21	28	115.91	3.04	38.12	25.37
2009	30,414	30,414	91,622	3,446,819	3,454,413	10,794.6	16	23	113.33	3.01	37.62	14.82
2010	26,949	26,949	79,306	2,968,881	2,973,457	9,324.9	14	20	110.17	2.94	37.44	15.01
2011	22,938	22,938	67,473	2,523,567	2,528,399	7,909.8	10	16	110.02	2.94	37.40	12.64
2012	23,503	23,503	64,632	2,334,198	2,337,886	7,348.8	11	15	99.31	2.75	36.12	14.97
2013	11,375	11,375	23,948	837,258	838,992	2,656.4	3	3	73.61	2.11	34.96	11.29
PE												
2003	3,229	3,229	14,830	538,665	631,393	1,626.6	17	19	166.82	4.59	36.32	104.52
2004	6,688	6,688	29,499	1,085,166	1,448,469	3,282.4	27	39	162.26	4.41	36.79	82.26
2005	5,406	5,406	20,014	838,412	843,244	2,549.1	12	13	155.09	3.70	41.89	47.08
2006	9,565	9,565	35,848	1,462,994	1,469,446	4,444.8	36	50	152.95	3.75	40.81	80.99
2007	14,502	14,502	49,188	1,964,844	1,969,214	6,037.9	56	74	135.49	3.39	39.95	92.75
2008	22,792	22,792	69,171	2,638,635	2,645,035	8,235.5	77	145	115.77	3.03	38.15	93.50
2009	30,359	30,359	91,441	3,439,932	3,447,585	10,722.3	90	137	113.31	3.01	37.62	83.94
2010	26,912	26,912	79,045	2,959,727	2,964,303	9,263.6	71	94	109.98	2.94	37.44	76.64
2011	22,903	22,903	67,356	2,519,343	2,524,175	7,878.2	77	135	110.00	2.94	37.40	97.74
2012	23,459	23,459	64,519	2,330,548	2,334,236	7,323.8	60	128	99.35	2.75	36.12	81.93

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk
2013	11,363	11,363	23,928	836,636	838,370	2,649.9	27	38	73.63	2.11	34.96	101.89
Stroke												
2003	3,233	3,233	14,840	538,965	631,693	1,631.2	7	7	166.71	4.59	36.32	42.91
2004	6,697	6,697	29,542	1,086,301	1,449,604	3,296.5	18	24	162.21	4.41	36.77	54.60
2005	5,404	5,404	20,010	838,273	843,105	2,550.4	7	8	155.12	3.70	41.89	27.45
2006	9,572	9,572	35,862	1,463,622	1,470,074	4,457.5	21	32	152.91	3.75	40.81	47.11
2007	14,514	14,514	49,270	1,967,044	1,971,422	6,066.3	28	41	135.53	3.39	39.92	46.16
2008	22,814	22,814	69,357	2,643,719	2,650,119	8,258.3	47	62	115.88	3.04	38.12	56.91
2009	30,404	30,404	91,596	3,445,541	3,453,135	10,766.1	41	58	113.33	3.01	37.62	38.08
2010	26,940	26,940	79,286	2,967,845	2,972,421	9,309.2	41	48	110.16	2.94	37.43	44.04
2011	22,924	22,924	67,393	2,520,818	2,525,650	7,890.9	34	46	109.96	2.94	37.40	43.09
2012	23,489	23,489	64,548	2,331,715	2,335,403	7,336.2	40	98	99.27	2.75	36.12	54.52
2013	11,372	11,372	23,942	837,016	838,750	2,653.5	13	23	73.60	2.11	34.96	48.99

Appendix A: ICD-9-CM Diagnosis Codes Used to Define AMI, ICJH, Stroke, and PE Events in this Report

Event	Description	Code
AMI	Acute myocardial infarction, episode of care unspecified	410.*0
AMI	Acute myocardial infarction, initial episode of care	410.*1
ICH	Subarachnoid hemorrhage	430*
ICH	Intracerebral hemorrhage	431*
ICH	Other and unspecified intracranial hemorrhage	432*
ICH	Subarachnoid hemorrhage following injury without mention of open intracranial wound	852.0*
ICH	Subdural hemorrhage following injury without mention of open intracranial wound	852.2*
ICH	Extradural hemorrhage following injury without mention of open intracranial wound	852.4*
ICH	Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wo	853.0*
Stroke	Occlusion and stenosis of precerebral arteries with cerebral infarction	433.*1
Stroke	Occlusion of cerebral arteries	434
Stroke	Cerebral thrombosis	434.0
Stroke	Cerebral embolism	434.1
Stroke	Cerebral artery occlusion unspecified	434.9
Stroke	Occlusion of cerebral arteries with cerebral infarction	434.*1
Stroke	Acute, but ill-defined, cerebrovascular disease	436*
PE	Pulmonary embolism and infarction	415.1*
PE	Phlebitis and thrombophlebitis	451.*
PE	Other venous embolism and thrombosis	453.*

* = wildcard match. Any value may be considered when used as a placeholder within a code. Signifies "starts with" when at end of code.