



## ***Modular Program Report***

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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<b>Overview</b>	
<b><u>Request Description</u></b>	<p>FDA requested execution of Modular Program #9 (MP9), version 3.0, to investigate prevalence and incidence of omalizumab and montelukast use among all eligible members and those with several pre-existing condition criteria (see specifications sheet for more detail) in the Mini-Sentinel Distributed Database (MSDD). This report presents results for Scenarios 7 and 13-19. Results for Scenarios 1-12 are presented in a separate report (TO09Y05_MPR_WP23, Report 1 of 2). The query was run against the MSDD for the time period of June 23, 2003 - May 31, 2013. The request was distributed to 18 Data Partners on March 4, 2014.</p> <p>Results provide counts of prevalent and incident number of users, new starts, dispensings, days supplied, amount supplied, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and users per 100,000 eligible members.</p>
<b><u>Request ID</u></b>	to09y05_mpr_wp23_v01, Report 2 of 2
<b><u>Specifications</u></b>	Program parameter inputs and scenarios.
<b><u>Glossary</u></b>	List of terms found in this report and their definitions.
<b><u>Table 1a</u></b>	Table displaying the number of prevalent users, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product and pre-existing condition criteria - June 23, 2003 - May 31, 2013.
<b><u>Table 1b</u></b>	Table displaying the number of incident users, new starts, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product and pre-existing condition criteria - June 23, 2003 - May 31, 2013.
<b><u>Table 2a</u></b>	Table displaying the number of prevalent users, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and age group - June 23, 2003 - May 31, 2013.
<b><u>Table 2b</u></b>	Table displaying the number of incident users, new starts, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and age group - June 23, 2003 - May 31, 2013.
<b><u>Table 3a</u></b>	Table displaying the number of prevalent users, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and sex - June 23, 2003 - May 31, 2013.
<b><u>Table 3b</u></b>	Table displaying the number of incident users, new starts, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and sex - June 23, 2003 - May 31, 2013.
<b><u>Table 4a</u></b>	Table displaying the number of prevalent users, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and year - June 23, 2003 - May 31, 2013.
<b><u>Table 4b</u></b>	Table displaying the number of incident users, new starts, dispensings, days supplied amount supplied, eligible members, member-years, days supplied per user, dispensings per user, days supplied per dispensing, and number of users per 100,000 eligible members by drug product, pre-existing condition criteria, and year - June 23, 2003 - May 31, 2013.

**Overview (Continued)**

<b><u>Table 5</u></b>	Table displaying Pre-existing Conditions and Prior Drug Exposures among Incident Omalizumab and Montelukast Users.
<b><u>Appendix A</u></b>	Exposure procedure (HCPCS).
<b><u>Appendix B</u></b>	Pre-existing condition criteria diagnosis code.
<b>Notes:</b>	Please contact the Mini-Sentinel Operations Center ( <a href="mailto:MSOC_Requests@harvardpilgrim.org">MSOC_Requests@harvardpilgrim.org</a> ) for questions and to provide comments/suggestions for future enhancements to this document.

**Modular Program Specifications for TO09Y05\_MPR\_WP23\_V01**

Modular Program #9 (MP9), version 3.0, was used to analyze prevalent and incident omalizumab or montelukast use among patients with differing pre-existing condition criteria. In total, 19 different scenarios were examined in this request. Report 2 presents scenarios 7 and 13-19 only.

**Coverage Requirement** Drug and Medical Coverage  
**Query Period** June 23, 2003 to May 31, 2013  
**Enrollment Gap** 45 Days  
**Age Stratifications** 0-8, 9-11, 12-17, 18-44, 45-64, 65+

Scenario	Drug/Exposure							Pre-Existing Condition					
	Incident exposure	Incident w/ respect to:	Enrollment Days	Washout (days)	Incidence Type*	Care Setting	Principal Diagnosis	Pre-Existing Condition	Include/Exclude	Lookback Start	Lookback End	Care Setting	Principal Diagnosis
1	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	none	NA	NA	NA	NA	NA
2	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	365	365	SING	All	All	none	NA	NA	NA	NA	NA
3	Omalizumab (NDC only)	Omalizumab (NDC only)	183	183	SING	All	All	none	NA	NA	NA	NA	NA
4	Omalizumab (NDC only)	Omalizumab (NDC only)	365	365	SING	All	All	none	NA	NA	NA	NA	NA
5	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	183	183	SING	All	All	none	NA	NA	NA	NA	NA
6	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	365	365	SING	All	All	none	NA	NA	NA	NA	NA
7	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	Asthma (493*)	Include	-183	-1	All	All
8	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	365	365	SING	All	All	Asthma (493*)	Include	-365	-1	All	All
9	Omalizumab (NDC only)	Omalizumab (NDC only)	183	183	SING	All	All	Asthma (493*)	Include	-183	-1	All	All

**Modular Program Specifications for TO09Y05\_MPR\_WP23\_V01**

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Scenario	Drug/Exposure							Pre-Existing Condition					
	Incident exposure	Incident w/ respect to:	Enrollment Days	Washout (days)	Incidence Type*	Care Setting	Principal Diagnosis	Pre-Existing Condition	Include/ Exclude	Lookback Start	Lookback End	Care Setting	Principal Diagnosis
<b>10</b>	Omalizumab (NDC only)	Omalizumab (NDC only)	365	365	SING	All	All	Asthma (493*)	Include	-365	-1	All	All
<b>11</b>	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	183	183	SING	All	All	Asthma (493*)	Include	-183	-1	All	All
<b>12</b>	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	365	365	SING	All	All	Asthma (493*)	Include	-365	-1	All	All
<b>13</b>	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	Asthma (493*) Inhaled corticosteroids (ICS only + ICS/LABA combination products)	Include Exclude	-183	-1	All	All
<b>14</b>	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	ICS/ LABA combo products	Include	-183	-1	All	All
<b>15</b>	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	ICS (no LABA combos) ICS/ LABA combo products	Include Exclude	-183	-1	All	All
<b>16</b>	Omalizumab (NDC and HCPCS J2357)	Omalizumab (NDC and HCPCS J2357)	183	183	SING	All	All	ICS (no LABA combos) LABA (no ICS combos) ICS/ LABA combo products	Include Exclude Exclude	-183	-1	All	All
<b>17</b>	Montelukast	Montelukast	183	183	SING	All	All	ICS/ LABA combo products	Include	-183	-1	All	All

**Modular Program Specifications for TO09Y05\_MPR\_WP23\_V01**

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Scenario	Drug/Exposure							Pre-Existing Condition					
	Incident exposure	Incident w/ respect to:	Enrollment Days	Washout (days)	Incidence Type*	Care Setting	Principal Diagnosis	Pre-Existing Condition	Include/ Exclude	Lookback Start	Lookback End	Care Setting	Principal Diagnosis
18	Montelukast	Montelukast	183	183	SING	All	All	ICS (no LABA combos)	Include	-183	-1	All	All
								ICS/ LABA combo products	Exclude				
19	Montelukast	Montelukast	183	183	SING	All	All	ICS (no LABA combos)	Include	-183	-1	All	All
								LABA (no ICS combos)	Exclude				
								ICS/ LABA combo products	Exclude				

\*Single incidence type for the exposure will only consider the first incident dispensing for each user during the query period that satisfies the Washout Period criteria (183 or 365 days).  
 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 9\*

**Amount Supplied** - Number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the Mini-Sentinel Common Data Model (MSCDM).

**Care Setting** - Contains the care settings considered for the individual diagnosis or procedure codes of interest. The following are valid entries:

IP: inpatient hospital stays

IS: non-acute institutional stays

ED: emergency department visits

AV: ambulatory visits

OA: other ambulatory visits.

**Days Supplied** - Number of days supplied for all dispensings encountered by individuals in the prevalent or incident cohort. The number is reported by the pharmacist as the number of days that the medications supports, based on the number of doses. (To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, once a member is included in the incident cohort, all dispensings for that individual are counted as dispensings.)

**Dispensings** - Total number of dispensings for members included in the prevalent- or incident-based cohort. To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, once a member is included in the incident cohort, all dispensings for that individual are counted as dispensings.

**Eligible Members (incidence-based cohort)** - Number of members eligible for incident diagnosis (defined by the washout period) with drug and/or medical coverage during the query period.

**Eligible Members (prevalence-based cohort)** - Number of members with at least one day of drug and/or medical coverage during the query period.

**Enrollment Gap** - Number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

**Exposure** - NDC and/or procedure and/or diagnosis code values for the exposure(s) of interest.

**Incidence Type (incidence-based cohort)** - *Minimum incidence type* will only consider the first claim in the query period as long as it is the first claim in the user's entire available history. *Single incidence type* will consider the first claim in the query period that satisfies the washout period criteria. That is, incidence is defined as the first claim during the query period with no evidence of a prior claim during the previous washout period days. *Multiple incidence type* will use the washout period to establish incidence and consider all qualifying incident claims.

**"Incident with Respect to" Codes** - NDC and/or procedure and/or diagnosis codes to be used to refine the incident definition for the exposure(s) of interest. For example, if a requester is examining exposure to DRUG A but wants incidence of DRUG A to be defined with respect to DRUG A and DRUG B, the Incident with Respect to Code fields would include both DRUG A and DRUG B codes.

**Incident Only Care Setting** - Contains the care settings considered for the individual diagnosis or procedure codes included as "Incident with Respect to" codes.

**Member-Years (incidence-based cohort)** - Sum of all years of enrollment with drug and/or medical coverage in the query period preceded by a washout period.

**Member-Years (prevalence-based cohort)** - Sum of all years members are enrolled with drug and/or medical coverage during the query period.

**New Starts**- Number of incident dispensings during the query period. Patient must have no prior dispensings of interest in the washout period. For a single and minimum incidence type, an individual may have no more than one new start. For a multiple incidence type, an individual may have more than one new start.

**New Users** - Number of members with incident claims during the query period. Member must have no evidence of claims of interest (defined by incidence criteria) in the prior washout period. A patient may only be counted once in a query period.

**Query Period** - Period in which the modular program looks for diagnoses of interest.

**Washout Period (incidence-based cohort)** - Number of days a patient is required to have no evidence of prior claim of interest and continuous drug and/or medical coverage.

\*all terms may not be used in this report

**Table 1a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product and Pre-existing Condition Criteria**

<b>Group</b>	<b>Users</b>	<b>Dispensings</b>	<b>Days Supplied</b>	<b>Amount Supplied</b>	<b>Eligible Members</b>	<b>Member-Years</b>	<b>Days Supplied per user</b>	<b>Dispensings per User</b>	<b>Days Supplied per Dispensing</b>	<b>Users per 100K Eligible Members</b>
<b>Omalizumab (NDC and Procedure Codes)</b>										
<i>Pre-existing Criteria</i>										
Asthma	15,803	248,426	3,572,451	538,579	8,350,957	8,487,128	226.06	15.72	14.38	189.24
Asthma excluding ICS only and ICS/LABA combination products	7,818	117,512	1,594,007	244,581	7,141,533	8,778,978	203.89	15.03	13.56	109.47
ICS/LABA combination products	9,948	156,861	2,360,550	351,869	2,541,223	3,212,556	237.29	15.77	15.05	391.47
ICS only excluding ICS/LABA combination products	2,569	44,014	656,675	93,920	3,219,955	3,517,241	255.62	17.13	14.92	79.78
ICS only excluding ICS/LABA combination and LABA only products	2,065	33,714	504,405	71,580	3,184,231	3,509,991	244.26	16.33	14.96	64.85
<b>Montelukast</b>										
<i>Pre-existing Criteria</i>										
ICS/LABA combination products	524,278	5,361,087	213,508,211	214,155,564	2,541,223	3,212,556	407.24	10.23	39.83	20,630.93
ICS only excluding ICS/LABA combination products	413,198	3,888,228	158,337,236	159,042,409	3,219,955	3,517,241	383.20	9.41	40.72	12,832.42
ICS only excluding ICS/LABA combination and LABA only products	397,384	3,643,667	146,434,526	147,052,078	3,184,231	3,509,991	368.50	9.17	40.19	12,479.75



**Table 1b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product and Pre-existing Condition Criteria**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>											
<i>Pre-existing Criteria</i>											
Asthma	8,073	8,073	8,130	150,207	23,683	7,953,628	7,564,250	18.61	1.01	18.48	101.50
Asthma excluding ICS and ICS/LABA combination products	2,555	2,555	2,575	46,428	6,744	7,138,277	8,760,576	18.17	1.01	18.03	35.79
ICS/LABA combination products	5,001	5,001	5,030	94,914	15,593	2,393,321	2,827,668	18.98	1.01	18.87	208.96
ICS only excluding ICS/LABA combination products	931	931	942	18,434	2,645	3,218,371	3,513,035	19.80	1.01	19.57	28.93
ICS only excluding ICS/LABA combination and LABA only products	655	655	664	12,975	1,827	3,182,791	3,506,118	19.81	1.01	19.54	20.58
<b>Montelukast</b>											
<i>Pre-existing Criteria</i>											
ICS/LABA combination products	187,823	187,823	187,901	7,352,941	7,370,681	2,106,905	2,148,392	39.15	1.00	39.13	8,914.64
ICS only excluding ICS/LABA combination products	184,301	184,301	184,368	7,430,014	7,447,964	2,974,441	2,965,669	40.31	1.00	40.30	6,196.16
ICS only excluding ICS/LABA combination and LABA only products	176,389	176,389	176,454	7,051,740	7,067,801	2,944,122	2,969,473	39.98	1.00	39.96	5,991.23

**Table 2a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Age Group**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>										
<i>Pre-existing Criteria</i>										
Asthma										
00-08 Months	71	444	8,345	1,117	1,425,679	1,258,138	117.54	6.25	18.80	4.98
09-11 Months	170	1,309	25,104	3,909	649,626	453,649	147.67	7.70	19.18	26.17
12-17 Years	1,120	13,346	220,746	35,273	981,370	774,052	197.09	11.92	16.54	114.13
18-44 Years	5,761	64,540	961,470	143,429	2,907,458	2,384,755	166.89	11.20	14.90	198.15
45-64 Years	8,164	134,924	2,054,887	297,748	2,302,133	2,397,125	251.70	16.53	15.23	354.63
65+ Years	1,719	33,863	301,899	57,103	975,826	1,219,385	175.62	19.70	8.92	176.16
Asthma excluding ICS only and ICS/LABA combination products										
00-08 Months	28	182	3,381	518	1,206,358	1,205,774	120.75	6.50	18.58	2.32
09-11 Months	71	574	11,124	1,722	558,141	504,744	156.68	8.08	19.38	12.72
12-17 Years	661	6,794	113,325	18,004	868,279	862,540	171.44	10.28	16.68	76.13
18-44 Years	2,896	30,953	446,786	66,834	2,470,095	2,315,829	154.28	10.69	14.43	117.24
45-64 Years	3,842	60,789	885,501	129,069	1,939,510	2,540,633	230.48	15.82	14.57	198.09
65+ Years	916	18,220	133,890	28,434	834,101	1,349,351	146.17	19.89	7.35	109.82
ICS/LABA combination products										
00-08 Months	29	225	3,855	541	67,044	55,529	132.93	7.76	17.13	43.26
09-11 Months	92	726	15,381	2,306	94,270	76,776	167.18	7.89	21.19	97.59
12-17 Years	683	8,411	145,890	23,106	182,550	171,303	213.60	12.31	17.35	374.14
18-44 Years	3,391	37,922	595,199	87,175	815,739	831,182	175.52	11.18	15.70	415.70
45-64 Years	5,429	89,122	1,394,614	202,449	1,038,263	1,306,572	256.88	16.42	15.65	522.89
65+ Years	1,072	20,455	205,611	36,292	546,847	771,195	191.80	19.08	10.05	196.03
ICS only excluding ICS/LABA combination products										
00-08 Months	16	84	2,206	151	836,354	734,769	137.88	5.25	26.26	1.91
09-11 Months	34	308	4,894	718	303,871	217,200	143.94	9.06	15.89	11.19
12-17 Years	190	2,014	37,974	5,600	347,284	274,721	199.86	10.60	18.86	54.71
18-44 Years	832	9,899	157,838	21,399	862,479	709,981	189.71	11.90	15.94	96.47
45-64 Years	1,390	24,541	385,487	53,677	840,042	987,102	277.33	17.66	15.71	165.47
65+ Years	331	7,168	68,276	12,375	399,004	593,449	206.27	21.66	9.53	82.96

**Table 2a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Age Group**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>										
ICS only excluding ICS/LABA combination and LABA only products										
00-08 Months	16	84	2,206	151	835,914	734,303	137.88	5.25	26.26	1.91
09-11 Months	30	272	4,125	595	303,339	217,137	137.50	9.07	15.17	9.89
12-17 Years	176	1,824	33,098	4,909	346,224	275,269	188.06	10.36	18.15	50.83
18-44 Years	695	8,125	129,909	17,505	854,114	712,239	186.92	11.69	15.99	81.37
45-64 Years	1,090	18,568	289,350	40,149	822,976	986,868	265.46	17.03	15.58	132.45
65+ Years	239	4,841	45,717	8,271	386,551	584,157	191.28	20.26	9.44	61.83
<b>Montelukast</b>										
<i>Pre-existing Criteria</i>										
ICS/LABA combination products										
00-08 Months	26,160	175,485	6,114,964	6,130,516	67,044	55,529	233.75	6.71	34.85	39,019.15
09-11 Months	33,960	209,435	7,449,609	7,484,762	94,270	76,776	219.36	6.17	35.57	36,024.19
12-17 Years	51,890	358,130	13,036,528	13,119,702	182,550	171,303	251.23	6.90	36.40	28,425.09
18-44 Years	160,793	1,271,407	47,729,885	47,866,378	815,739	831,182	296.84	7.91	37.54	19,711.33
45-64 Years	222,343	2,463,488	100,314,477	100,631,789	1,038,263	1,306,572	451.17	11.08	40.72	21,414.90
65+ Years	82,139	883,142	38,862,748	38,922,417	546,847	771,195	473.13	10.75	44.01	15,020.47
ICS only excluding ICS/LABA combination products										
00-08 Months	157,364	1,154,096	41,048,004	41,097,665	836,354	734,769	260.85	7.33	35.57	18,815.48
09-11 Months	62,814	386,747	14,391,190	14,452,027	303,871	217,200	229.11	6.16	37.21	20,671.27
12-17 Years	51,684	344,177	13,167,896	13,290,248	347,284	274,721	254.78	6.66	38.26	14,882.34
18-44 Years	75,219	589,045	23,985,488	24,134,470	862,479	709,981	318.88	7.83	40.72	8,721.26
45-64 Years	91,828	1,033,722	46,708,148	46,969,143	840,042	987,102	508.65	11.26	45.18	10,931.36
65+ Years	33,741	380,441	19,036,510	19,098,856	399,004	593,449	564.20	11.28	50.04	8,456.31

**Table 2a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Age Group**

<b>Group</b>	<b>Users</b>	<b>Dispensings</b>	<b>Days Supplied</b>	<b>Amount Supplied</b>	<b>Eligible Members</b>	<b>Member-Years</b>	<b>Days Supplied per user</b>	<b>Dispensings per User</b>	<b>Days Supplied per Dispensing</b>	<b>Users per 100K Eligible Members</b>
<b>Montelukast (Continued)</b>										
ICS only excluding ICS/LABA combination and LABA only products										
00-08 Months	156,993	1,150,911	40,928,973	40,977,449	835,914	734,303	260.71	7.33	35.56	18,781.00
09-11 Months	62,400	383,515	14,263,419	14,323,939	303,339	217,137	228.58	6.15	37.19	20,571.04
12-17 Years	50,974	337,469	12,888,710	13,004,602	346,224	275,269	252.85	6.62	38.19	14,722.84
18-44 Years	71,360	547,522	22,087,278	22,219,258	854,114	712,239	309.52	7.67	40.34	8,354.86
45-64 Years	83,217	900,946	40,238,146	40,451,722	822,976	986,868	483.53	10.83	44.66	10,111.72
65+ Years	29,707	323,304	16,028,000	16,075,108	386,551	584,157	539.54	10.88	49.58	7,685.14

**Table 2b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Age Group**

<b>Group</b>	<b>New Users</b>	<b>New Starts</b>	<b>Dispensings</b>	<b>Days Supplied</b>	<b>Amount Supplied</b>	<b>Eligible Members</b>	<b>Member-Years</b>	<b>Days Supplied per user</b>	<b>Dispensings per User</b>	<b>Days Supplied per Dispensing</b>	<b>New Users per 100K Eligible Members</b>
<b>Omalizumab (NDC and Procedure Codes)</b>											
<i>Pre-existing Criteria</i>											
Asthma											
00-08 Months	36	36	36	873	106	1,342,619	1,101,707	24.25	1.00	24.25	2.68
09-11 Months	66	66	67	1,591	250	616,557	406,336	24.11	1.02	23.75	10.70
12-17 Years	562	562	566	11,481	1,767	941,899	697,810	20.43	1.01	20.28	59.67
18-44 Years	2,797	2,797	2,812	52,986	7,696	2,734,929	2,069,218	18.94	1.01	18.84	102.27
45-64 Years	3,854	3,854	3,877	73,794	12,306	2,204,648	2,158,657	19.15	1.01	19.03	174.81
65+ Years	758	758	772	9,482	1,558	940,601	1,130,499	12.51	1.02	12.28	80.59
Asthma excluding ICS only and ICS/LABA combination products											
00-08 Months	12	12	12	257	47	1,206,340	1,205,729	21.42	1.00	21.42	0.99
09-11 Months	21	21	22	705	110	558,088	504,622	33.57	1.05	32.05	3.76
12-17 Years	185	185	185	4,003	645	867,956	861,328	21.64	1.00	21.64	21.31
18-44 Years	971	971	977	17,980	2,577	2,468,746	2,310,452	18.52	1.01	18.40	39.33
45-64 Years	1,099	1,099	1,107	20,682	2,875	1,937,615	2,531,222	18.82	1.01	18.68	56.72
65+ Years	267	267	272	2,801	490	833,689	1,347,115	10.49	1.02	10.30	32.03
ICS/LABA combination products											
00-08 Months	17	17	17	425	54	60,922	47,071	25.00	1.00	25.00	27.90
09-11 Months	41	41	41	855	119	87,054	65,988	20.85	1.00	20.85	47.10
12-17 Years	335	335	336	6,405	990	172,117	149,360	19.12	1.00	19.06	194.64
18-44 Years	1,655	1,655	1,664	31,834	4,600	757,913	708,786	19.24	1.01	19.13	218.36
45-64 Years	2,517	2,517	2,528	49,379	8,880	977,645	1,154,553	19.62	1.00	19.53	257.46
65+ Years	436	436	444	6,016	950	517,292	701,909	13.80	1.02	13.55	84.29
ICS only excluding ICS/LABA combination products											
00-08 Months	8	8	8	219	11	836,345	734,758	27.38	1.00	27.38	0.96
09-11 Months	9	9	9	200	38	303,844	217,157	22.22	1.00	22.22	2.96
12-17 Years	70	70	73	1,768	237	347,160	274,495	25.26	1.04	24.22	20.16
18-44 Years	317	317	318	6,267	929	861,942	708,944	19.77	1.00	19.71	36.78
45-64 Years	429	429	434	8,696	1,215	839,104	984,727	20.27	1.01	20.04	51.13
65+ Years	98	98	100	1,284	215	398,779	592,935	13.10	1.02	12.84	24.58

**Table 2b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Age Group**

<b>Group</b>	<b>New Users</b>	<b>New Starts</b>	<b>Dispensings</b>	<b>Days Supplied</b>	<b>Amount Supplied</b>	<b>Eligible Members</b>	<b>Member-Years</b>	<b>Days Supplied per user</b>	<b>Dispensings per User</b>	<b>Days Supplied per Dispensing</b>	<b>New Users per 100K Eligible Members</b>
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>											
ICS only excluding ICS/LABA combination and LABA only products											
00-08 Months	8	8	8	219	11	835,905	734,292	27.38	1.00	27.38	0.96
09-11 Months	7	7	7	198	36	303,316	217,097	28.29	1.00	28.29	2.31
12-17 Years	60	60	63	1,347	180	346,101	275,035	22.45	1.05	21.38	17.34
18-44 Years	244	244	245	4,941	732	853,610	711,241	20.25	1.00	20.17	28.58
45-64 Years	275	275	278	5,555	735	822,142	984,743	20.20	1.01	19.98	33.45
65+ Years	61	61	63	715	133	386,366	583,691	11.72	1.03	11.35	15.79
<b>Montelukast</b>											
<i>Pre-existing Criteria</i>											
ICS/LABA combination products											
00-08 Months	5,888	5,888	5,889	212,166	212,531	42,458	25,610	36.03	1.00	36.03	13,867.82
09-11 Months	7,264	7,264	7,270	273,685	274,887	62,507	38,194	37.68	1.00	37.65	11,621.10
12-17 Years	14,445	14,445	14,450	547,632	550,622	137,466	97,536	37.91	1.00	37.90	10,508.05
18-44 Years	55,696	55,696	55,713	2,055,415	2,061,224	661,938	536,496	36.90	1.00	36.89	8,414.08
45-64 Years	74,995	74,995	75,034	2,992,995	2,999,464	853,202	863,691	39.91	1.00	39.89	8,789.83
65+ Years	29,535	29,535	29,545	1,271,048	1,271,953	474,919	586,865	43.04	1.00	43.02	6,218.96
ICS only excluding ICS/LABA combination products											
00-08 Months	75,396	75,396	75,430	2,764,422	2,764,057	749,270	565,427	36.67	1.00	36.65	10,062.59
09-11 Months	15,695	15,695	15,699	640,921	643,539	253,394	161,782	40.84	1.00	40.83	6,193.91
12-17 Years	15,507	15,507	15,511	656,682	660,754	307,565	222,234	42.35	1.00	42.34	5,041.86
18-44 Years	29,903	29,903	29,913	1,228,300	1,232,735	807,370	624,667	41.08	1.00	41.06	3,703.75
45-64 Years	34,747	34,747	34,759	1,525,330	1,531,371	779,841	852,600	43.90	1.00	43.88	4,455.65
65+ Years	13,053	13,053	13,056	614,359	615,508	378,697	538,942	47.07	1.00	47.06	3,446.82

**Table 2b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Age Group**

<b>Group</b>	<b>New Users</b>	<b>New Starts</b>	<b>Dispensings</b>	<b>Days Supplied</b>	<b>Amount Supplied</b>	<b>Eligible Members</b>	<b>Member-Years</b>	<b>Days Supplied per user</b>	<b>Dispensings per User</b>	<b>Days Supplied per Dispensing</b>	<b>New Users per 100K Eligible Members</b>
<b>Montelukast (Continued)</b>											
ICS only excluding ICS/LABA combination and LABA only products											
00-08 Months	75,248	75,248	75,282	2,758,597	2,758,198	748,954	565,241	36.66	1.00	36.64	10,047.08
09-11 Months	15,594	15,594	15,598	636,635	639,229	253,054	161,834	40.83	1.00	40.82	6,162.32
12-17 Years	15,266	15,266	15,270	646,110	650,052	306,813	222,900	42.32	1.00	42.31	4,975.67
18-44 Years	28,148	28,148	28,158	1,145,013	1,148,795	800,428	628,504	40.68	1.00	40.66	3,516.62
45-64 Years	30,842	30,842	30,853	1,337,231	1,342,627	766,076	857,974	43.36	1.00	43.34	4,025.97
65+ Years	11,291	11,291	11,293	528,154	528,900	367,854	533,002	46.78	1.00	46.77	3,069.42

**Table 3a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Sex**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>										
<i>Pre-existing Criteria</i>										
Asthma										
Female	9,888	154,667	2,279,919	324,999	4,723,113	4,948,036	230.57	15.64	14.74	209.35
Male	5,912	93,737	1,292,452	213,556	3,625,432	3,537,057	218.62	15.86	13.79	163.07
Unknown	3	22	80	24	2,412	2,034	26.67	7.33	3.64	124.38
Asthma excluding ICS only and ICS/LABA combination products										
Female	5,088	76,523	1,064,313	155,002	4,057,738	5,174,068	209.18	15.04	13.91	125.39
Male	2,729	40,987	529,634	89,575	3,081,788	3,602,961	194.08	15.02	12.92	88.55
Unknown	1	2	60	4	2,007	1,948	60	2	30	49.83
ICS/LABA combination products										
Female	6,070	95,730	1,484,269	209,216	1,464,362	1,834,839	244.53	15.77	15.50	414.51
Male	3,877	61,116	876,266	142,638	1,076,099	1,376,999	226.02	15.76	14.34	360.28
Unknown	1	15	15	15	762	718	15	15	1	131.23
ICS only excluding ICS/LABA combination products										
Female	1,610	27,485	420,398	57,156	1,733,598	1,923,067	261.1167702	17.07	15.30	92.87
Male	959	16,529	236,277	36,764	1,485,777	1,593,691	246.3785193	17.24	14.29	64.55
Unknown	0	0	0	0	580	482	0	0	0	0.00
ICS only excluding ICS/LABA combination and LABA only products										
Female	1,311	21,427	328,341	44,016	1,713,067	1,924,687	250.45	16.34	15.32	76.53
Male	754	12,287	176,064	27,564	1,470,594	1,584,836	233.51	16.30	14.33	51.27
Unknown	0	0	0	0	570	469	0	0	0	0.00



Table 3a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Sex

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Montelukast</b>										
<i>Pre-existing Criteria</i>										
ICS/LABA combination products										
Female	324,127	3,396,051	136,245,278	#####	1,464,362	1,834,839	420.35	10.48	40.12	22,134.35
Male	200,019	1,963,636	77,213,673	77,437,210	1,076,099	1,376,999	386.03	9.82	39.32	18,587.42
Unknown	132	1,400	49,260	49,440	762	718	373.18	10.61	35.19	17,322.83
ICS only excluding ICS/LABA combination products										
Female	215,534	2,109,468	88,492,508	88,916,696	1,733,598	1,923,067	410.57	9.79	41.95	12,432.76
Male	197,595	1,778,005	69,814,218	70,094,873	1,485,777	1,593,691	353.32	9	39.27	13,299.10
Unknown	69	755	30,510	30,840	580	482	442.17	10.94	40.41	11,896.55
ICS only excluding ICS/LABA combination and LABA only products										
Female	205,308	1,948,129	80,630,589	81,004,583	1,713,067	1,924,687	392.73	9.49	41.39	11,984.82
Male	192,011	1,694,805	65,774,447	66,017,765	1,470,594	1,584,836	342.56	8.83	38.81	13,056.70
Unknown	65	733	29,490	29,730	570	469	453.69	11.28	40.23	11,403.51

**Table 3b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Sex**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>											
<i>Pre-existing Criteria</i>											
Asthma											
Female	5,047	5,047	5,083	94,418	14,864	4,496,820	4,414,462	18.71	1.01	18.58	112.23
Male	3,025	3,025	3,046	55,759	8,817	3,454,694	3,148,029	18.43	1.01	18.31	87.56
Unknown	1	1	1	30	2	2,114	1,759	30	1	30	47.30
Asthma excluding ICS only and ICS/LABA combination products											
Female	1,683	1,683	1,697	30,290	4,179	4,055,623	5,162,187	18.00	1.01	17.85	41.50
Male	871	871	877	16,108	2,563	3,080,647	3,596,440	18.49	1.01	18.37	28.27
Unknown	1	1	1	30	2	2,007	1,948	30	1	30	49.83
ICS/LABA combination products											
Female	3,039	3,039	3,054	59,309	9,983	1,380,758	1,616,970	19.52	1.00	19.42	220.10
Male	1,962	1,962	1,976	35,605	5,610	1,011,956	1,210,050	18.15	1.01	18.02	193.88
Unknown	0	0	0	0	0	607	649	0	0	0	0.00
ICS only excluding ICS/LABA combination products											
Female	587	587	595	11,219	1,536	1,732,587	1,920,411	19.11	1.01	18.86	33.88
Male	344	344	347	7,215	1,109	1,485,204	1,592,143	20.97	1.01	20.79	23.16
Unknown	0	0	0	0	0	580	482	0	0	0	0.00
ICS only excluding ICS/LABA combination and LABA only products											
Female	418	418	424	8,051	1,077	1,712,139	1,922,241	19.26	1.01	18.99	24.41
Male	237	237	240	4,924	750	1,470,082	1,583,408	20.78	1.01	20.52	16.12
Unknown	0	0	0	0	0	570	469	0	0	0	0.00

**Table 3b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Sex**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Montelukast</b>											
<i>Pre-existing Criteria</i>											
ICS/LABA combination products											
Female	116,389	116,389	116,438	4,574,523	4,585,757	1,203,614	1,200,358	39.30	1	39.29	9,669.96
Male	71,385	71,385	71,414	2,776,768	2,783,184	902,754	947,554	38.90	1	38.88	7,907.47
Unknown	49	49	49	1,650	1,740	537	480	33.67	1	33.67	9,124.77
ICS only excluding ICS/LABA combination products											
Female	94,322	94,322	94,352	3,877,298	3,887,614	1,602,460	1,630,762	41.11	1	41.09	5,886.08
Male	89,949	89,949	89,986	3,551,816	3,559,450	1,371,445	1,334,502	39.49	1	39.47	6,558.70
Unknown	30	30	30	900	900	536	405	30	1	30	5,597.01
ICS only excluding ICS/LABA combination and LABA only products											
Female	89,184	89,184	89,213	3,630,895	3,640,121	1,585,412	1,638,693	40.71	1	40.70	5,625.29
Male	87,176	87,176	87,212	3,419,975	3,426,810	1,358,184	1,330,388	39.23	1	39.21	6,418.57
Unknown	29	29	29	870	870	526	392	30	1	30	5,513.31

**Table 4a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Year**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>										
<i>Pre-existing Criteria</i>										
Asthma										
2003	29	77	2,228	292	337,281	99,602	76.83	2.66	28.94	8.60
2004	101	579	16,428	1,897	449,205	202,447	162.65	5.73	28.37	22.48
2005	197	1,508	25,489	3,464	521,890	242,394	129.39	7.65	16.90	37.75
2006	1,764	10,389	235,302	31,240	1,091,215	502,029	133.39	5.89	22.65	161.65
2007	2,205	12,971	274,945	36,939	1,353,246	615,442	124.69	5.88	21.20	162.94
2008	5,793	41,683	586,451	91,208	2,564,215	1,183,462	101.23	7.20	14.07	225.92
2009	5,801	42,845	607,802	91,099	2,875,900	1,332,347	104.78	7.39	14.19	201.71
2010	5,405	39,905	558,532	84,553	2,828,285	1,321,891	103.34	7.38	14.00	191.11
2011	5,363	40,607	535,155	82,487	2,739,146	1,288,130	99.79	7.57	13.18	195.79
2012	5,247	41,420	528,086	82,991	2,646,583	1,237,183	100.65	7.89	12.75	198.26
2013	4,055	16,442	202,033	32,409	1,790,356	462,202	49.82	4.05	12.29	226.49
Asthma excluding ICS only and ICS/LABA combination products										
2003	6	15	420	51	280,520	81,056	70.00	2.50	28.00	2.14
2004	38	166	4,629	545	380,966	197,106	121.82	4.37	27.89	9.97
2005	80	553	9,285	1,262	453,509	287,562	116.06	6.91	16.79	17.64
2006	598	2,549	49,062	6,838	921,102	467,849	82.04	4.26	19.25	64.92
2007	914	5,226	98,671	13,725	1,178,843	672,420	107.96	5.72	18.88	77.53
2008	2,457	13,370	197,822	30,080	2,149,259	1,047,513	80.51	5.44	14.80	114.32
2009	3,003	20,924	283,948	43,043	2,499,781	1,382,169	94.55	6.97	13.57	120.13
2010	2,887	20,172	278,219	42,312	2,471,356	1,448,683	96.37	6.99	13.79	116.82
2011	3,003	21,954	280,692	43,794	2,396,956	1,442,676	93.47	7.31	12.79	125.28
2012	3,044	23,311	283,231	45,327	2,276,571	1,323,991	93.05	7.66	12.15	133.71
2013	2,270	9,272	108,028	17,604	1,405,222	427,953	47.59	4.08	11.65	161.54

**Table 4a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Year**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>										
ICS/LABA combination products										
2003	19	47	1,388	201	31,923	11,384	73.05	2.47	29.53	59.52
2004	57	366	10,389	1,280	54,378	30,211	182.26	6.42	28.39	104.82
2005	121	858	16,866	2,224	72,138	41,959	139.39	7.09	19.66	167.73
2006	961	5,220	132,237	16,734	294,429	168,263	137.60	5.43	25.33	326.39
2007	1,335	7,350	167,513	22,164	390,196	216,661	125.48	5.51	22.79	342.14
2008	3,236	21,682	339,343	51,254	845,747	477,070	104.86	6.70	15.65	382.62
2009	3,708	27,008	406,881	60,199	947,384	542,083	109.73	7.28	15.07	391.39
2010	3,691	27,086	390,371	58,931	933,288	546,219	105.76	7.34	14.41	395.48
2011	3,628	27,503	375,814	57,331	861,614	508,165	103.59	7.58	13.66	421.07
2012	3,568	28,469	376,426	58,687	833,145	484,881	105.50	7.98	13.22	428.26
2013	2,748	11,272	143,322	22,864	627,570	185,660	52.16	4.10	12.71	437.88
ICS only excluding ICS/LABA combination products										
2003	4	13	364	38	289,099	93,270	91.00	3.25	28.00	1.38
2004	17	116	3,234	310	363,701	188,648	190.24	6.82	27.88	4.67
2005	35	320	4,691	491	392,751	209,096	134.03	9.14	14.66	8.91
2006	294	1,339	26,348	3,400	557,106	261,470	89.62	4.55	19.68	52.77
2007	425	2,695	56,038	7,439	604,521	304,458	131.85	6.34	20.79	70.30
2008	894	5,259	85,684	12,034	893,969	401,662	95.84	5.88	16.29	100.00
2009	1,017	7,810	116,161	16,344	1,005,305	494,596	114.22	7.68	14.87	101.16
2010	977	7,421	108,326	15,561	1,005,816	496,260	110.88	7.60	14.60	97.14
2011	994	7,858	108,773	16,067	962,163	475,162	109.43	7.91	13.84	103.31
2012	1,024	8,057	107,804	16,165	907,618	439,288	105.28	7.87	13.38	112.82
2013	750	3,126	39,252	6,071	577,366	153,331	52.34	4.17	12.56	129.90

**Table 4a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Year**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>										
ICS only excluding ICS/LABA combination and LABA only products										
2003	3	9	252	34	276,544	87,906	84.00	3.00	28.00	1.08
2004	10	73	2,044	173	351,225	182,284	204.40	7.30	28.00	2.85
2005	14	107	2,356	208	382,191	207,126	168.29	7.64	22.02	3.66
2006	156	634	13,220	1,657	543,746	260,684	84.74	4.06	20.85	28.69
2007	288	1,672	37,005	4,703	592,676	304,821	128.49	5.81	22.13	48.59
2008	647	3,646	60,497	8,230	878,512	401,549	93.50	5.64	16.59	73.65
2009	769	5,882	87,343	12,187	992,029	494,974	113.58	7.65	14.85	77.52
2010	784	5,754	86,076	12,224	995,152	498,239	109.79	7.34	14.96	78.78
2011	826	6,438	89,974	13,219	953,192	477,789	108.93	7.79	13.98	86.66
2012	875	6,788	91,294	13,671	899,947	441,295	104.34	7.76	13.45	97.23
2013	652	2,711	34,344	5,274	571,960	153,324	52.67	4.16	12.67	113.99
<b>Montelukast</b>										
<i>Pre-existing Criteria</i>										
ICS/LABA combination products										
2003	4,887	14,956	573,587	579,436	31,923	11,384	117.37	3.06	38.35	15,308.71
2004	9,098	40,572	1,632,811	1,646,048	54,378	30,211	179.47	4.46	40.24	16,731.03
2005	12,442	55,219	2,300,777	2,320,601	72,138	41,959	184.92	4.44	41.67	17,247.50
2006	63,328	277,717	11,205,079	11,256,027	294,429	168,263	176.94	4.39	40.35	21,508.75
2007	85,759	389,677	15,368,970	15,427,392	390,196	216,661	179.21	4.54	39.44	21,978.44
2008	179,528	792,748	30,467,445	30,568,225	845,747	477,070	169.71	4.42	38.43	21,227.15
2009	194,163	901,651	35,541,128	35,640,841	947,384	542,083	183.05	4.64	39.42	20,494.65
2010	190,129	893,976	35,527,027	35,626,570	933,288	546,219	186.86	4.70	39.74	20,371.95
2011	177,612	841,171	33,943,443	34,039,740	861,614	508,165	191.11	4.74	40.35	20,613.87
2012	173,867	820,818	33,466,742	33,545,638	833,145	484,881	192.48	4.72	40.77	20,868.76
2013	132,152	332,582	13,481,202	13,505,046	627,570	185,660	102.01	2.52	40.53	21,057.73

**Table 4a. Summary of Prevalent Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Criteria, and Year**

Group	Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	Users per 100K Eligible Members
<b>Montelukast (Continued)</b>										
ICS only excluding ICS/LABA combination products										
2003	9,917	26,645	1,213,315	1,223,120	289,099	93,270	122.35	2.69	45.54	3,430.31
2004	16,660	67,006	3,141,154	3,163,799	363,701	188,648	188.54	4.02	46.88	4,580.69
2005	20,749	82,594	3,922,385	3,958,151	392,751	209,096	189.04	3.98	47.49	5,282.99
2006	52,079	174,361	7,806,940	7,871,861	557,106	261,470	149.91	3.35	44.77	9,348.13
2007	74,698	315,694	13,253,472	13,337,084	604,521	304,458	177.43	4.23	41.98	12,356.56
2008	123,444	465,004	18,604,098	18,697,395	893,969	401,662	150.71	3.77	40.01	13,808.53
2009	147,326	635,291	25,184,647	25,280,562	1,005,305	494,596	170.95	4.31	39.64	14,654.86
2010	149,485	644,964	25,720,117	25,822,280	1,005,816	496,260	172.06	4.31	39.88	14,862.06
2011	144,666	627,155	25,292,263	25,390,982	962,163	475,162	174.83	4.34	40.33	15,035.50
2012	141,093	609,662	24,692,032	24,767,704	907,618	439,288	175.01	4.32	40.50	15,545.42
2013	99,519	239,852	9,506,813	9,529,471	577,366	153,331	95.53	2.41	39.64	17,236.73
ICS only excluding ICS/LABA combination and LABA only products										
2003	7,231	19,184	836,693	842,802	276,544	87,906	115.71	2.65	43.61	2,614.77
2004	13,208	52,323	2,379,893	2,396,078	351,225	182,284	180.19	3.96	45.48	3,760.55
2005	17,308	67,449	3,128,964	3,157,385	382,191	207,126	180.78	3.90	46.39	4,528.63
2006	46,432	152,129	6,688,979	6,743,335	543,746	260,684	144.06	3.28	43.97	8,539.28
2007	68,862	286,904	11,867,406	11,939,897	592,676	304,821	172.34	4.17	41.36	11,618.83
2008	115,776	430,695	16,989,986	17,071,042	878,512	401,549	146.75	3.72	39.45	13,178.65
2009	140,300	599,439	23,486,987	23,573,648	992,029	494,974	167.41	4.27	39.18	14,142.73
2010	143,514	614,171	24,252,415	24,344,009	995,152	498,239	168.99	4.28	39.49	14,421.31
2011	139,630	601,260	24,030,284	24,121,068	953,192	477,789	172.10	4.31	39.97	14,648.68
2012	136,716	587,715	23,622,223	23,691,926	899,947	441,295	172.78	4.30	40.19	15,191.56
2013	96,390	232,398	9,150,696	9,170,888	571,960	153,324	94.93	2.41	39.38	16,852.58

**Table 4b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Year**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes)</b>											
<i>Pre-existing Criteria</i>											
Asthma											
2003	25	25	25	764	100	327,797	94,619	30.56	1.00	30.56	7.63
2004	58	58	58	1,597	194	435,347	187,414	27.53	1.00	27.53	13.32
2005	97	97	97	1,488	230	504,756	226,555	15.34	1.00	15.34	19.22
2006	375	375	376	13,102	1,623	1,027,558	383,451	34.94	1.00	34.85	36.49
2007	611	611	618	22,939	3,008	1,296,487	549,593	37.54	1.01	37.12	47.13
2008	1,180	1,180	1,194	21,529	4,988	2,404,999	922,535	18.24	1.01	18.03	49.06
2009	1,524	1,524	1,539	22,945	3,568	2,774,455	1,226,784	15.06	1.01	14.91	54.93
2010	1,280	1,280	1,288	19,216	2,940	2,731,774	1,220,170	15.01	1.01	14.92	46.86
2011	1,287	1,287	1,297	20,268	3,053	2,640,701	1,188,564	15.75	1.01	15.63	48.74
2012	1,194	1,194	1,195	18,665	2,851	2,552,157	1,143,899	15.63	1.00	15.62	46.78
2013	442	442	443	7,694	1,128	1,638,981	420,666	17.41	1.00	17.37	26.97
Asthma excluding ICS only and ICS/LABA combination products											
2003	5	5	5	140	19	280,518	81,053	28.00	1.00	28.00	1.78
2004	20	20	20	539	72	380,940	197,069	26.95	1.00	26.95	5.25
2005	25	25	25	297	55	453,448	287,469	11.88	1.00	11.88	5.51
2006	105	105	106	3,172	440	920,269	467,310	30.21	1.01	29.92	11.41
2007	165	165	166	6,211	791	1,177,819	671,322	37.64	1.01	37.42	14.01
2008	391	391	398	7,504	1,071	2,146,452	1,045,263	19.19	1.02	18.85	18.22
2009	484	484	489	7,337	1,097	2,496,835	1,378,858	15.16	1.01	15.00	19.38
2010	389	389	391	5,988	899	2,468,438	1,445,402	15.39	1.01	15.31	15.76
2011	443	443	447	6,839	1,076	2,394,006	1,439,295	15.44	1.01	15.30	18.50
2012	389	389	389	5,876	849	2,273,600	1,320,726	15.11	1.00	15.11	17.11
2013	139	139	139	2,525	375	1,402,632	426,809	18.17	1.00	18.17	9.91



**Table 4b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Year**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>											
ICS/LABA combination products											
2003	16	16	16	512	70	30,655	10,573	32.00	1.00	32.00	52.19
2004	31	31	31	876	98	51,867	27,459	28.26	1.00	28.26	59.77
2005	58	58	58	986	142	68,911	38,948	17.00	1.00	17.00	84.17
2006	225	225	225	8,493	1,013	270,503	110,797	37.75	1.00	37.75	83.18
2007	371	371	373	13,912	1,797	371,100	186,759	37.50	1.01	37.30	99.97
2008	677	677	683	12,404	3,744	785,372	360,597	18.32	1.01	18.16	86.20
2009	952	952	962	14,248	2,234	911,243	499,808	14.97	1.01	14.81	104.47
2010	840	840	845	13,060	1,993	898,465	503,785	15.55	1.01	15.46	93.49
2011	797	797	801	12,824	1,861	829,359	470,715	16.09	1.01	16.01	96.10
2012	747	747	748	12,473	1,933	801,655	449,403	16.70	1.00	16.68	93.18
2013	287	287	288	5,126	708	566,582	168,826	17.86	1.00	17.80	50.65
ICS only excluding ICS/LABA combination products											
2003	4	4	4	112	11	289,097	93,269	28.00	1.00	28.00	1.38
2004	7	7	7	182	24	363,688	188,637	26.00	1.00	26.00	1.92
2005	14	14	14	205	33	392,724	209,065	14.64	1.00	14.64	3.56
2006	62	62	62	2,136	275	556,779	261,305	34.45	1.00	34.45	11.14
2007	92	92	96	3,631	519	604,119	304,130	39.47	1.04	37.82	15.23
2008	152	152	155	2,900	347	893,080	401,113	19.08	1.02	18.71	17.02
2009	152	152	153	2,571	419	1,004,382	493,845	16.91	1.01	16.80	15.13
2010	129	129	130	1,736	278	1,004,945	495,535	13.46	1.01	13.35	12.84
2011	138	138	140	2,469	353	961,300	474,454	17.89	1.01	17.64	14.36
2012	130	130	130	1,764	263	906,770	438,600	13.57	1.00	13.57	14.34
2013	51	51	51	728	123	576,729	153,080	14.27	1.00	14.27	8.84

**Table 4b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Year**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Omalizumab (NDC and Procedure Codes) (Continued)</b>											
ICS only excluding ICS/LABA combination and LABA only products											
2003	3	3	3	84	10	276,543	87,905	28.00	1.00	28.00	1.08
2004	4	4	4	112	12	351,215	182,275	28.00	1.00	28.00	1.14
2005	3	3	3	86	14	382,173	207,102	28.67	1.00	28.67	0.78
2006	31	31	31	1,210	165	543,481	260,548	39.03	1.00	39.03	5.70
2007	58	58	60	2,357	313	592,344	304,543	40.64	1.03	39.28	9.79
2008	104	104	107	2,096	246	877,748	401,069	20.15	1.03	19.59	11.85
2009	99	99	100	1,621	259	991,218	494,293	16.37	1.01	16.21	9.99
2010	92	92	93	1,427	216	994,378	497,569	15.51	1.01	15.34	9.25
2011	113	113	115	1,934	264	952,414	477,115	17.12	1.02	16.82	11.86
2012	106	106	106	1,491	227	899,160	440,620	14.07	1.00	14.07	11.79
2013	42	42	42	557	101	571,360	153,080	13.26	1.00	13.26	7.35
<b>Montelukast</b>											
<i>Pre-existing Criteria</i>											
ICS/LABA combination products											
2003	843	843	843	34,280	34,737	25,700	8,382	40.66	1.00	40.66	3,280.16
2004	2,070	2,070	2,070	87,226	87,578	44,355	21,942	42.14	1.00	42.14	4,666.89
2005	2,795	2,795	2,796	119,715	120,648	58,802	31,015	42.83	1.00	42.82	4,753.24
2006	9,156	9,156	9,156	378,829	379,910	216,349	83,659	41.37	1.00	41.37	4,232.05
2007	14,997	14,997	14,998	599,337	601,047	298,299	138,852	39.96	1.00	39.96	5,027.51
2008	25,065	25,065	25,077	972,306	975,507	630,462	270,187	38.79	1.00	38.77	3,975.66
2009	34,787	34,787	34,797	1,334,581	1,337,736	746,273	378,706	38.36	1.00	38.35	4,661.43
2010	31,775	31,775	31,794	1,217,620	1,220,241	736,664	384,552	38.32	1.00	38.30	4,313.36
2011	26,866	26,866	26,876	1,050,462	1,052,046	676,660	359,599	39.10	1.00	39.09	3,970.38
2012	27,234	27,234	27,248	1,072,139	1,074,132	653,665	343,684	39.37	1.00	39.35	4,166.35
2013	12,235	12,235	12,246	486,446	487,099	445,427	127,813	39.76	1.00	39.72	2,746.80

**Table 4b. Summary of Incident Omalizumab and Montelukast Use in the MSDD between June 23, 2003 and May 31, 2013, by Drug Product, Pre-existing Condition Criteria, and Year**

Group	New Users	New Starts	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	Days Supplied per user	Dispensings per User	Days Supplied per Dispensing	New Users per 100K Eligible Members
<b>Montelukast (Continued)</b>											
ICS only excluding ICS/LABA combination products											
2003	2,548	2,548	2,548	120,597	121,225	278,432	88,500	47.33	1.00	47.33	915.12
2004	5,369	5,369	5,371	261,664	262,980	350,424	177,800	48.74	1.00	48.72	1,532.14
2005	5,901	5,901	5,903	276,677	277,784	376,210	195,241	46.89	1.00	46.87	1,568.54
2006	12,059	12,059	12,061	549,931	552,191	504,068	232,233	45.60	1.00	45.60	2,392.34
2007	16,977	16,977	16,980	733,073	735,169	535,582	257,535	43.18	1.00	43.17	3,169.82
2008	21,980	21,980	21,985	882,413	884,250	766,944	329,549	40.15	1.00	40.14	2,865.92
2009	30,474	30,474	30,482	1,157,291	1,158,326	872,961	403,381	37.98	1.00	37.97	3,490.88
2010	28,463	28,463	28,474	1,090,358	1,093,332	875,329	406,641	38.31	1.00	38.29	3,251.69
2011	25,058	25,058	25,070	973,958	975,837	836,863	390,106	38.87	1.00	38.85	2,994.28
2012	24,527	24,527	24,545	962,975	964,959	787,585	360,473	39.26	1.00	39.23	3,114.20
2013	10,945	10,945	10,949	421,077	421,911	487,164	124,211	38.47	1.00	38.46	2,246.68
ICS only excluding ICS/LABA combination and LABA only products											
2003	1,950	1,950	1,950	90,491	90,767	266,989	83,717	46.41	1.00	46.41	730.37
2004	4,285	4,285	4,287	205,189	206,141	339,305	172,374	47.89	1.00	47.86	1,262.88
2005	5,059	5,059	5,061	237,013	237,640	367,438	194,066	46.85	1.00	46.83	1,376.83
2006	11,061	11,061	11,063	499,734	501,818	493,883	232,538	45.18	1.00	45.17	2,239.60
2007	15,972	15,972	15,975	682,191	684,097	527,197	259,159	42.71	1.00	42.70	3,029.61
2008	21,085	21,085	21,090	839,104	841,150	756,364	331,180	39.80	1.00	39.79	2,787.68
2009	29,584	29,584	29,592	1,117,961	1,119,102	864,126	405,492	37.79	1.00	37.78	3,423.57
2010	27,796	27,796	27,807	1,061,654	1,064,154	868,551	409,861	38.19	1.00	38.18	3,200.27
2011	24,631	24,631	24,643	955,084	956,925	831,243	393,525	38.78	1.00	38.76	2,963.15
2012	24,155	24,155	24,171	947,487	949,341	782,670	363,067	39.23	1.00	39.20	3,086.23
2013	10,811	10,811	10,815	415,832	416,666	483,724	124,495	38.46	1.00	38.45	2,234.95

**Table 5. Incident Omalizumab and Montelukast Users by Pre-existing Criteria**

Condition/Drug Product	N, (%)
<b>Omalizumab Users</b> with Asthma	8,073 (100.0%)
with Asthma and prior ICS only or ICS/LABA combination product use	5,518 (68.4%)
<b>Omalizumab Users</b> with prior ICS and LABA use	5,277
<b>Montelukast Users</b> with prior ICS and LABA use	195,735

**Appendix A. HCPCS for Exposure Included in this Request**

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<b>Description</b>	<b>HCPCS</b>
OMALIZUMAB	J2357

**Appendix B. ICD-9 Diagnosis Code for Pre-existing Condition Criteria Included in this Request**

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<b>Description</b>	<b>Diagnosis Code</b>
Asthma	493*