



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).

If you are using a web page screen reader and are unable to access this document, please contact the Mini-Sentinel Operations Center for assistance at info@mini-sentinel.org.

Overview	
<u>Request Description</u>	<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 1-12. Results for Scenarios 7 and 13-19 are presented in a separate report (TO09Y05_MPR_WP23, Report 2 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>
<u>Request ID</u>	to09y05_mpr_wp23_v01 - Report 1 of 2
<u>Specifications</u>	Program parameter inputs and scenarios.
<u>Glossary</u>	List of terms found in this report and their definitions.
<u>Table 1a</u>	Table displaying the number of prevalent omalizumab 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 pre-existing condition criteria, code type, and washout period - June 23, 2003 - May 31, 2013.
<u>Table 1b</u>	Table displaying the number of incident omalizumab 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 pre-existing condition criteria, code type, and washout period - June 23, 2003 - May 31, 2013.
<u>Table 2a</u>	Table displaying the number of prevalent omalizumab 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 pre-existing condition criteria, code type, washout period, and age group - June 23, 2003 - May 31, 2013.
<u>Table 2b</u>	Table displaying the number of incident omalizumab 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 pre-existing condition criteria, code type, washout period, and age group - June 23, 2003 - May 31, 2013.
<u>Table 3a</u>	Table displaying the number of prevalent omalizumab 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 pre-existing condition criteria, code type, washout period, and sex - June 23, 2003 - May 31, 2013.
<u>Table 3b</u>	Table displaying the number of incident omalizumab 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 pre-existing condition criteria, code type, washout period, and sex - June 23, 2003 - May 31, 2013.
<u>Table 4a</u>	Table displaying the number of prevalent omalizumab 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 pre-existing condition criteria, code type, washout period, and year - June 23, 2003 - May 31, 2013.
<u>Table 4b</u>	Table displaying the number of incident omalizumab 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 pre-existing condition criteria, code type, washout period, and year - June 23, 2003 - May 31, 2013.

Overview (Continued)

Appendix A Exposure procedure (HCPCS).

Appendix B Pre-existing condition criteria diagnosis codes.

Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications 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 1 presents scenarios 1-12 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

10	Omalizumab (NDC only)	Omalizumab (NDC only)	365	365	SING	All	All	Asthma (493*)	Include	-365	-1	All	All
11	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	183	183	SING	All	All	Asthma (493*)	Include	-183	-1	All	All
12	Omalizumab (HCPCS J2357 only)	Omalizumab (HCPCS J2357 only)	365	365	SING	All	All	Asthma (493*)	Include	-365	-1	All	All
13	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>Asthma (493*) Inhaled corticosteroids (ICS include LABA combination products)</i>	<i>Include Exclude</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
14	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS/ LABA combo products</i>	<i>Include</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
15	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS (no LABA combos) ICS/ LABA combo products</i>	<i>Include Exclude</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
16	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>Omalizumab (NDC and HCPCS J2357)</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS (no LABA combos) LABA (no ICS combos) ICS/ LABA combo products</i>	<i>Include Exclude Exclude</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
17	<i>Montelukast</i>	<i>Montelukast</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS/ LABA combo products</i>	<i>Include</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
18	<i>Montelukast</i>	<i>Montelukast</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS (no LABA combos) ICS/ LABA combo products</i>	<i>Include Exclude</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>
19	<i>Montelukast</i>	<i>Montelukast</i>	<i>183</i>	<i>183</i>	<i>SING</i>	<i>All</i>	<i>All</i>	<i>ICS (no LABA combos) LABA (no ICS combos) ICS/ LABA combo products</i>	<i>Include Exclude Exclude</i>	<i>-183</i>	<i>-1</i>	<i>All</i>	<i>All</i>

*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 Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, and Washout Period

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
No Pre-existing Condition Criteria										
<i>NDCs and Procedure Codes</i>										
183 day washout period	16,491	254,581	3,694,583	553,983	108,520,893	271,868,837	224.04	15.44	14.51	15.20
365 day washout period	16,491	254,581	3,694,583	553,983	108,520,893	271,868,837	224.04	15.44	14.51	15.20
<i>NDCs only</i>										
183 day washout period	8,862	112,547	3,552,549	411,949	108,520,893	271,868,837	400.87	12.70	31.57	8.17
365 day washout period	8,862	112,547	3,552,549	411,949	108,520,893	271,868,837	400.87	12.70	31.57	8.17
<i>Procedure codes only</i>										
183 day washout period	9,699	142,034	142,034	142,034	108,520,893	271,868,837	14.64	14.64	1.00	8.94
365 day washout period	9,699	142,034	142,034	142,034	108,520,893	271,868,837	14.64	14.64	1.00	8.94
Pre-existing Asthma										
<i>NDCs and Procedure Codes</i>										
183 day washout period	15,803	248,426	3,572,451	538,579	8,350,957	8,487,128	226.06	15.72	14.38	189.24
365 day washout period	15,834	248,584	3,575,756	538,988	8,383,044	12,494,079	225.83	15.70	14.38	188.88
<i>NDCs only</i>										
183 day washout period	8,500	108,970	3,432,252	399,090	8,350,957	8,487,128	403.79	12.82	31.50	101.78
365 day washout period	8,515	109,058	3,435,514	399,432	8,383,044	12,494,079	403.47	12.81	31.50	101.57
<i>Procedure codes only</i>										
183 day washout period	9,292	139,363	139,363	139,363	8,350,957	8,487,128	15.00	15.00	1.00	111.27
365 day washout period	9,316	139,486	139,486	139,486	8,383,044	12,494,079	14.97	14.97	1.00	111.13

Table 1b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, and Washout Period

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
No Pre-existing Condition Criteria											
<i>NDCs and Procedure Codes</i>											
183 day washout period	8,623	8,623	8,682	158,635	24,974	89,287,800	219,446,983	18.40	1.01	18.27	9.66
365 day washout period	6,178	6,178	6,226	106,101	15,609	72,733,237	178,112,970	17.17	1.01	17.04	8.49
<i>NDCs only</i>											
183 day washout period	4,788	4,788	4,788	167,762	22,432	89,289,753	219,459,846	35.04	1.00	35.04	5.36
365 day washout period	3,416	3,416	3,416	113,668	13,899	72,735,665	178,123,906	33.28	1.00	33.28	4.70
<i>Procedure codes only</i>											
183 day washout period	5,434	5,434	5,474	5,474	5,474	89,289,874	219,459,874	1.01	1.01	1.00	6.09
365 day washout period	4,103	4,103	4,135	4,135	4,135	72,735,760	178,123,823	1.01	1.01	1.00	5.64
Pre-existing Asthma											
<i>NDCs and Procedure Codes</i>											
183 day washout period	8,073	8,073	8,130	150,207	23,683	7,953,628	7,564,250	18.61	1.01	18.48	101.50
365 day washout period	5,862	5,862	5,909	102,066	14,987	7,262,906	9,859,372	17.41	1.01	17.27	80.71
<i>NDCs only</i>											
183 day washout period	4,554	4,554	4,554	159,489	21,455	7,955,746	7,576,145	35.02	1.00	35.02	57.24
365 day washout period	3,297	3,297	3,297	109,777	13,479	7,265,458	9,869,908	33.30	1.00	33.30	45.38
<i>Procedure codes only</i>											
183 day washout period	5,080	5,080	5,118	5,118	5,118	7,955,786	7,575,848	1.01	1.01	1.00	63.85
365 day washout period	3,892	3,892	3,923	3,923	3,923	7,265,456	9,869,721	1.01	1.01	1.00	53.57

Table 2a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
00 to 08 Years	79	471	8,723	1,153	14,403,192	27,757,578	110.42	5.96	18.52	0.55
09 to 11 Years	182	1,367	26,356	4,110	7,076,253	10,271,733	144.81	7.51	19.28	2.57
12-17 Years	1,157	13,692	228,662	36,246	11,350,903	21,869,440	197.63	11.83	16.70	10.19
18-44 Years	6,061	66,679	1,006,637	149,038	51,436,778	103,940,615	166.08	11.00	15.10	11.78
45-64 Years	8,457	137,909	2,115,628	305,240	30,947,460	79,440,493	250.16	16.31	15.34	27.33
65+ Years	1,790	34,463	308,577	58,196	9,319,348	28,576,936	172.39	19.25	8.95	19.21
365 day washout period										
00 to 08 Years	79	471	8,723	1,153	14,403,192	27,757,578	110.42	5.96	18.52	0.55
09 to 11 Years	182	1,367	26,356	4,110	7,076,253	10,271,733	144.81	7.51	19.28	2.57
12-17 Years	1,157	13,692	228,662	36,246	11,350,903	21,869,440	197.63	11.83	16.70	10.19
18-44 Years	6,061	66,679	1,006,637	149,038	51,436,778	103,940,615	166.08	11.00	15.10	11.78
45-64 Years	8,457	137,909	2,115,628	305,240	30,947,460	79,440,493	250.16	16.31	15.34	27.33
65+ Years	1,790	34,463	308,577	58,196	9,319,348	28,576,936	172.39	19.25	8.95	19.21
<i>NDCs only</i>										
183 day washout period										
00 to 08 Years	43	248	8,500	930	14,403,192	27,757,578	197.67	5.77	34.27	0.30
09 to 11 Years	111	797	25,786	3,540	7,076,253	10,271,733	232.31	7.18	32.35	1.57
12-17 Years	659	7,079	222,049	29,633	11,350,903	21,869,440	336.95	10.74	31.37	5.81
18-44 Years	3,297	30,648	970,606	113,007	51,436,778	103,940,615	294.39	9.30	31.67	6.41
45-64 Years	4,674	64,514	2,042,233	231,845	30,947,460	79,440,493	436.93	13.80	31.66	15.10
65+ Years	735	9,261	283,375	32,994	9,319,348	28,576,936	385.54	12.60	30.60	7.89
365 day washout period										
00 to 08 Years	43	248	8,500	930	14,403,192	27,757,578	197.67	5.77	34.27	0.30
09 to 11 Years	111	797	25,786	3,540	7,076,253	10,271,733	232.31	7.18	32.35	1.57
12-17 Years	659	7,079	222,049	29,633	11,350,903	21,869,440	336.95	10.74	31.37	5.81
18-44 Years	3,297	30,648	970,606	113,007	51,436,778	103,940,615	294.39	9.30	31.67	6.41
45-64 Years	4,674	64,514	2,042,233	231,845	30,947,460	79,440,493	436.93	13.80	31.66	15.10
65+ Years	735	9,261	283,375	32,994	9,319,348	28,576,936	385.54	12.60	30.60	7.89

Table 2a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria (Continued)										
<i>Procedure codes only</i>										
183 day washout period										
00 to 08 Years	42	223	223	223	14,403,192	27,757,578	5.31	5.31	1.00	0.29
09 to 11 Years	82	570	570	570	7,076,253	10,271,733	6.95	6.95	1.00	1.16
12-17 Years	621	6,613	6,613	6,613	11,350,903	21,869,440	10.65	10.65	1.00	5.47
18-44 Years	3,366	36,031	36,031	36,031	51,436,778	103,940,615	10.70	10.70	1.00	6.54
45-64 Years	4,913	73,395	73,395	73,395	30,947,460	79,440,493	14.94	14.94	1.00	15.88
65+ Years	1,271	25,202	25,202	25,202	9,319,348	28,576,936	19.83	19.83	1.00	13.64
365 day washout period										
00 to 08 Years	42	223	223	223	14,403,192	27,757,578	5.31	5.31	1.00	0.29
09 to 11 Years	82	570	570	570	7,076,253	10,271,733	6.95	6.95	1.00	1.16
12-17 Years	621	6,613	6,613	6,613	11,350,903	21,869,440	10.65	10.65	1.00	5.47
18-44 Years	3,366	36,031	36,031	36,031	51,436,778	103,940,615	10.70	10.70	1.00	6.54
45-64 Years	4,913	73,395	73,395	73,395	30,947,460	79,440,493	14.94	14.94	1.00	15.88
65+ Years	1,271	25,202	25,202	25,202	9,319,348	28,576,936	19.83	19.83	1.00	13.64
Pre-existing Asthma										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
00 to 08 Years	71	444	8,345	1,117	1,425,679	1,258,138	117.54	6.25	18.80	4.98
09 to 11 Years	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
365 day washout period										
00 to 08 Years	71	444	8,345	1,117	1,431,114	1,802,385	117.54	6.25	18.80	4.96
09 to 11 Years	171	1,310	25,132	3,911	689,115	675,369	146.97	7.66	19.18	24.81
12-17 Years	1,120	13,351	220,861	35,292	1,024,362	1,197,896	197.20	11.92	16.54	109.34
18-44 Years	5,774	64,606	963,211	143,621	2,956,471	3,598,995	166.82	11.19	14.91	195.30
45-64 Years	8,178	134,991	2,056,154	297,923	2,336,747	3,506,815	251.43	16.51	15.23	349.97
65+ Years	1,722	33,882	302,053	57,124	994,388	1,712,524	175.41	19.68	8.91	173.17

Table 2a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma (Continued)										
<i>NDCs only</i>										
183 day washout period										
00 to 08 Years	42	235	8,136	908	1,425,679	1,258,138	193.71	5.60	34.62	2.95
09 to 11 Years	102	755	24,550	3,355	649,626	453,649	240.69	7.40	32.52	15.70
12-17 Years	634	6,864	214,264	28,791	981,370	774,052	337.96	10.83	31.22	64.60
18-44 Years	3,124	29,388	926,318	108,277	2,907,458	2,384,755	296.52	9.41	31.52	107.45
45-64 Years	4,520	62,669	1,981,889	225,460	2,302,133	2,397,125	438.47	13.86	31.62	196.34
65+ Years	714	9,059	277,095	32,299	975,826	1,219,385	388.09	12.69	30.59	73.17
365 day washout period										
00 to 08 Years	42	235	8,136	908	1,431,114	1,802,385	193.71	5.60	34.62	2.93
09 to 11 Years	103	756	24,578	3,357	689,115	675,369	238.62	7.34	32.51	14.95
12-17 Years	634	6,866	214,376	28,807	1,024,362	1,197,896	338.13	10.83	31.22	61.89
18-44 Years	3,131	29,433	928,038	108,448	2,956,471	3,598,995	296.40	9.40	31.53	105.90
45-64 Years	4,527	62,704	1,983,151	225,606	2,336,747	3,506,815	438.07	13.85	31.63	193.73
65+ Years	714	9,064	277,235	32,306	994,388	1,712,524	388.28	12.69	30.59	71.80
<i>Procedure codes only</i>										
183 day washout period										
00 to 08 Years	35	209	209	209	1,425,679	1,258,138	5.97	5.97	1.00	2.45
09 to 11 Years	78	554	554	554	649,626	453,649	7.10	7.10	1.00	12.01
12-17 Years	607	6,482	6,482	6,482	981,370	774,052	10.68	10.68	1.00	61.85
18-44 Years	3,207	35,122	35,122	35,122	2,907,458	2,384,755	10.95	10.95	1.00	110.30
45-64 Years	4,733	72,196	72,196	72,196	2,302,133	2,397,125	15.25	15.25	1.00	205.59
65+ Years	1,215	24,800	24,800	24,800	975,826	1,219,385	20.41	20.41	1.00	124.51
365 day washout period										
00 to 08 Years	35	209	209	209	1,431,114	1,802,385	5.97	5.97	1.00	2.45
09 to 11 Years	78	554	554	554	689,115	675,369	7.10	7.10	1.00	11.32
12-17 Years	607	6,485	6,485	6,485	1,024,362	1,197,896	10.68	10.68	1.00	59.26
18-44 Years	3,215	35,168	35,168	35,168	2,956,471	3,598,995	10.94	10.94	1.00	108.74
45-64 Years	4,745	72,253	72,253	72,253	2,336,747	3,506,815	15.23	15.23	1.00	203.06
65+ Years	1,219	24,817	24,817	24,817	994,388	1,712,524	20.36	20.36	1.00	122.59

Table 2b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, and Age Group

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
No Pre-existing Condition Criteria											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
00 to 08 Years	40	40	40	904	111	11,018,673	20,933,635	22.60	1.00	22.60	0.36
09 to 11 Years	73	73	74	1,793	280	5,825,300	8,321,267	24.56	1.01	24.23	1.25
12-17 Years	589	589	593	11,991	1,840	9,431,015	17,882,311	20.36	1.01	20.22	6.25
18-44 Years	3,018	3,018	3,033	56,680	8,227	41,062,904	80,484,942	18.78	1.00	18.69	7.35
45-64 Years	4,075	4,075	4,099	77,307	12,848	26,407,108	66,651,884	18.97	1.01	18.86	15.43
65+ Years	828	828	843	9,960	1,668	8,333,706	25,161,517	12.03	1.02	11.81	9.94
365 day washout period											
00 to 08 Years	27	27	27	564	81	8,459,071	15,843,948	20.89	1.00	20.89	0.32
09 to 11 Years	52	52	53	1,145	185	4,762,768	6,763,266	22.02	1.02	21.60	1.09
12-17 Years	432	432	435	8,151	1,204	7,796,537	14,667,724	18.87	1.01	18.74	5.54
18-44 Years	2,096	2,096	2,107	36,782	5,355	32,058,195	62,793,081	17.55	1.01	17.46	6.54
45-64 Years	2,920	2,920	2,941	52,080	7,519	22,582,538	55,916,324	17.84	1.01	17.71	12.93
65+ Years	651	651	663	7,379	1,265	7,585,350	22,117,863	11.33	1.02	11.13	8.58
<i>NDCs only</i>											
183 day washout period											
00 to 08 Years	26	26	26	917	98	11,018,680	20,933,657	35.27	1.00	35.27	0.24
09 to 11 Years	49	49	49	1,768	255	5,825,329	8,321,322	36.08	1.00	36.08	0.84
12-17 Years	364	364	364	12,580	1,714	9,431,178	17,882,897	34.56	1.00	34.56	3.86
18-44 Years	1,686	1,686	1,686	58,910	7,195	41,063,650	80,488,627	34.94	1.00	34.94	4.11
45-64 Years	2,335	2,335	2,335	82,748	11,864	26,408,380	66,658,397	35.44	1.00	35.44	8.84
65+ Years	328	328	328	10,839	1,306	8,334,064	25,163,519	33.05	1.00	33.05	3.94
365 day washout period											
00 to 08 Years	16	16	16	553	70	8,459,077	15,843,961	34.56	1.00	34.56	0.19
09 to 11 Years	32	32	32	1,124	164	4,762,794	6,763,314	35.13	1.00	35.13	0.67
12-17 Years	265	265	265	8,662	1,110	7,796,705	14,668,219	32.69	1.00	32.69	3.40
18-44 Years	1,164	1,164	1,164	38,815	4,680	32,059,050	62,796,139	33.35	1.00	33.35	3.63
45-64 Years	1,683	1,683	1,683	56,341	6,884	22,584,024	55,921,879	33.48	1.00	33.48	7.45
65+ Years	256	256	256	8,173	991	7,585,741	22,119,631	31.93	1.00	31.93	3.37

Table 2b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, and Age Group

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
No Pre-existing Condition Criteria (Continued)											
<i>Procedure codes only</i>											
183 day washout period											
00 to 08 Years	20	20	20	20	20	11,018,683	20,933,666	1.00	1.00	1.00	0.18
09 to 11 Years	32	32	32	32	32	5,825,336	8,321,367	1.00	1.00	1.00	0.55
12-17 Years	328	328	329	329	329	9,431,203	17,883,118	1.00	1.00	1.00	3.48
18-44 Years	1,763	1,763	1,772	1,772	1,772	41,063,727	80,488,871	1.01	1.01	1.00	4.29
45-64 Years	2,612	2,612	2,625	2,625	2,625	26,408,563	66,658,968	1.00	1.00	1.00	9.89
65+ Years	679	679	696	696	696	8,334,028	25,162,456	1.03	1.03	1.00	8.15
365 day washout period											
00 to 08 Years	13	13	13	13	13	8,459,080	15,843,973	1.00	1.00	1.00	0.15
09 to 11 Years	28	28	28	28	28	4,762,809	6,763,352	1.00	1.00	1.00	0.59
12-17 Years	250	250	251	251	251	7,796,749	14,668,402	1.00	1.00	1.00	3.21
18-44 Years	1,286	1,286	1,291	1,291	1,291	32,059,114	62,796,311	1.00	1.00	1.00	4.01
45-64 Years	1,972	1,972	1,984	1,984	1,984	22,584,186	55,922,320	1.01	1.01	1.00	8.73
65+ Years	554	554	568	568	568	7,585,678	22,118,703	1.03	1.03	1.00	7.30
Pre-existing Asthma											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
00 to 08 Years	36	36	36	873	106	1,342,619	1,101,707	24.25	1.00	24.25	2.68
09 to 11 Years	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
365 day washout period											
00 to 08 Years	25	25	25	562	79	1,190,472	1,346,449	22.48	1.00	22.48	2.10
09 to 11 Years	47	47	48	1,055	175	589,891	534,575	22.45	1.02	21.98	7.97
12-17 Years	416	416	419	7,828	1,167	902,512	965,969	18.82	1.01	18.68	46.09
18-44 Years	1,976	1,976	1,987	35,111	5,101	2,468,999	2,702,029	17.77	1.01	17.67	80.03
45-64 Years	2,792	2,792	2,812	50,448	7,264	2,069,177	2,843,175	18.07	1.01	17.94	134.93
65+ Years	606	606	618	7,062	1,201	911,885	1,467,081	11.65	1.02	11.43	66.46

Table 2b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, and Age Group

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
Pre-existing Asthma (Continued)											
<i>NDCs only</i>											
183 day washout period											
00 to 08 Years	25	25	25	889	96	1,342,628	1,101,722	35.56	1.00	35.56	1.86
09 to 11 Years	44	44	44	1,568	227	616,586	406,390	35.64	1.00	35.64	7.14
12-17 Years	350	350	350	12,056	1,654	942,077	698,365	34.45	1.00	34.45	37.15
18-44 Years	1,588	1,588	1,588	55,284	6,786	2,735,755	2,072,578	34.81	1.00	34.81	58.05
45-64 Years	2,232	2,232	2,232	79,273	11,438	2,205,963	2,164,744	35.52	1.00	35.52	101.18
65+ Years	315	315	315	10,419	1,254	940,967	1,132,323	33.08	1.00	33.08	33.48
365 day washout period											
00 to 08 Years	16	16	16	553	70	1,190,480	1,346,461	34.56	1.00	34.56	1.34
09 to 11 Years	29	29	29	1,036	156	589,916	534,620	35.72	1.00	35.72	4.92
12-17 Years	257	257	257	8,320	1,081	902,693	966,451	32.37	1.00	32.37	28.47
18-44 Years	1,117	1,117	1,117	37,217	4,503	2,469,912	2,704,971	33.32	1.00	33.32	45.22
45-64 Years	1,630	1,630	1,630	54,758	6,705	2,070,704	2,848,553	33.59	1.00	33.59	78.72
65+ Years	248	248	248	7,893	964	912,287	1,468,756	31.83	1.00	31.83	27.18
<i>Procedure codes only</i>											
183 day washout period											
00 to 08 Years	17	17	17	17	17	1,342,629	1,101,735	1.00	1.00	1.00	1.27
09 to 11 Years	30	30	30	30	30	616,594	406,429	1.00	1.00	1.00	4.87
12-17 Years	314	314	315	315	315	942,086	698,555	1.00	1.00	1.00	33.33
18-44 Years	1,627	1,627	1,636	1,636	1,636	2,735,796	2,072,630	1.01	1.01	1.00	59.47
45-64 Years	2,476	2,476	2,488	2,488	2,488	2,206,121	2,165,110	1.00	1.00	1.00	112.23
65+ Years	616	616	632	632	632	940,913	1,131,366	1.03	1.03	1.00	65.47
365 day washout period											
00 to 08 Years	11	11	11	11	11	1,190,481	1,346,473	1.00	1.00	1.00	0.92
09 to 11 Years	26	26	26	26	26	589,931	534,655	1.00	1.00	1.00	4.41
12-17 Years	242	242	243	243	243	902,723	966,622	1.00	1.00	1.00	26.81
18-44 Years	1,209	1,209	1,214	1,214	1,214	2,469,936	2,705,054	1.00	1.00	1.00	48.95
45-64 Years	1,889	1,889	1,900	1,900	1,900	2,070,829	2,848,931	1.01	1.01	1.00	91.22
65+ Years	515	515	529	529	529	912,208	1,467,891	1.03	1.03	1.00	56.46

Table 3a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
Female	10,307	158,412	2,356,174	334,118	54,755,089	139,141,846	228.60	15.37	14.87	18.82
Male	6,181	96,147	1,338,329	219,841	53,730,089	132,668,277	216.52	15.56	13.92	11.50
Unknown	3	22	80	24	35,715	58,715	26.67	7.33	3.64	8.40
365 day washout period										
Female	10,307	158,412	2,356,174	334,118	54,755,089	139,141,846	228.60	15.37	14.87	18.82
Male	6,181	96,147	1,338,329	219,841	53,730,089	132,668,277	216.52	15.56	13.92	11.50
Unknown	3	22	80	24	35,715	58,715	26.67	7.33	3.64	8.40
<i>NDCs only</i>										
183 day washout period										
Female	5,549	71,288	2,269,050	246,994	54,755,089	139,141,846	408.91	12.85	31.83	10.13
Male	3,312	41,257	1,283,439	164,951	53,730,089	132,668,277	387.51	12.46	31.11	6.16
Unknown	1	2	60	4	35,715	58,715	60.00	2.00	30.00	2.80
365 day washout period										
Female	5,549	71,288	2,269,050	246,994	54,755,089	139,141,846	408.91	12.85	31.83	10.13
Male	3,312	41,257	1,283,439	164,951	53,730,089	132,668,277	387.51	12.46	31.11	6.16
Unknown	1	2	60	4	35,715	58,715	60.00	2.00	30.00	2.80
<i>Procedure codes only</i>										
183 day washout period										
Female	6,057	87,124	87,124	87,124	54,755,089	139,141,846	14.38	14.38	1.00	11.06
Male	3,640	54,890	54,890	54,890	53,730,089	132,668,277	15.08	15.08	1.00	6.77
Unknown	2	20	20	20	35,715	58,715	10.00	10.00	1.00	5.60
365 day washout period										
Female	6,057	87,124	87,124	87,124	54,755,089	139,141,846	14.38	14.38	1.00	11.06
Male	3,640	54,890	54,890	54,890	53,730,089	132,668,277	15.08	15.08	1.00	6.77
Unknown	2	20	20	20	35,715	58,715	10.00	10.00	1.00	5.60

Table 3a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
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
365 day washout period										
Female	9,912	154,775	2,282,630	325,305	4,740,572	7,228,300	230.29	15.61	14.75	209.09
Male	5,919	93,787	1,293,046	213,659	3,640,060	5,262,933	218.46	15.85	13.79	162.61
Unknown	3	22	80	24	2,412	2,846	26.67	7.33	3.64	124.38
<i>NDCs only</i>										
183 day washout period										
Female	5,323	69,067	2,193,576	239,366	4,723,113	4,948,036	412.09	12.98	31.76	112.70
Male	3,176	39,901	1,238,616	159,720	3,625,432	3,537,057	389.99	12.56	31.04	87.60
Unknown	1	2	60	4	2,412	2,034	60.00	2.00	30.00	41.46
365 day washout period										
Female	5,335	69,137	2,196,276	239,637	4,740,572	7,228,300	411.67	12.96	31.77	112.54
Male	3,179	39,919	1,239,178	159,791	3,640,060	5,262,933	389.80	12.56	31.04	87.33
Unknown	1	2	60	4	2,412	2,846	60.00	2.00	30.00	41.46
<i>Procedure codes only</i>										
183 day washout period										
Female	5,806	85,512	85,512	85,512	4,723,113	4,948,036	14.73	14.73	1.00	122.93
Male	3,484	53,831	53,831	53,831	3,625,432	3,537,057	15.45	15.45	1.00	96.10
Unknown	2	20	20	20	2,412	2,034	10.00	10.00	1.00	82.92
365 day washout period										
Female	5,826	85,600	85,600	85,600	4,740,572	7,228,300	14.69	14.69	1.00	122.90
Male	3,488	53,866	53,866	53,866	3,640,060	5,262,933	15.44	15.44	1.00	95.82
Unknown	2	20	20	20	2,412	2,846	10.00	10.00	1.00	82.92

Table 3b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
Female	5,376	5,376	5,412	99,577	15,617	45,295,070	112,677,172	18.52	1.01	18.40	11.87
Male	3,246	3,246	3,269	59,028	9,355	43,972,104	106,727,556	18.18	1.01	18.06	7.38
Unknown	1	1	1	30	2	20,626	42,255	30.00	1.00	30.00	4.85
365 day washout period											
Female	3,860	3,860	3,889	66,346	9,231	36,992,378	91,721,676	17.19	1.01	17.06	10.43
Male	2,317	2,317	2,336	39,725	6,376	35,722,813	86,360,164	17.15	1.01	17.01	6.49
Unknown	1	1	1	30	2	18,046	31,129	30.00	1.00	30.00	5.54
<i>NDCs only</i>											
183 day washout period											
Female	2,972	2,972	2,972	104,807	13,973	45,296,292	112,685,113	35.26	1.00	35.26	6.56
Male	1,815	1,815	1,815	62,925	8,457	43,972,834	106,732,477	34.67	1.00	34.67	4.13
Unknown	1	1	1	30	2	20,627	42,256	30.00	1.00	30.00	4.85
365 day washout period											
Female	2,119	2,119	2,119	70,523	8,102	36,993,894	91,728,432	33.28	1.00	33.28	5.73
Male	1,296	1,296	1,296	43,115	5,795	35,723,724	86,364,344	33.27	1.00	33.27	3.63
Unknown	1	1	1	30	2	18,047	31,130	30.00	1.00	30.00	5.54
<i>Procedure codes only</i>											
183 day washout period											
Female	3,389	3,389	3,417	3,417	3,417	45,296,359	112,685,231	1.01	1.01	1.00	7.48
Male	2,045	2,045	2,057	2,057	2,057	43,972,889	106,732,388	1.01	1.01	1.00	4.65
Unknown	0	0	0	0	0	20,626	42,255	0.00	0.00	0.00	0.00
365 day washout period											
Female	2,568	2,568	2,591	2,591	2,591	36,993,985	91,728,490	1.01	1.01	1.00	6.94
Male	1,535	1,535	1,544	1,544	1,544	35,723,729	86,364,204	1.01	1.01	1.00	4.30
Unknown	0	0	0	0	0	18,046	31,130	0.00	0.00	0.00	0.00

Table 3b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
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	30.00	1.00	30.00	47.30
365 day washout period											
Female	3,673	3,673	3,702	64,090	8,887	4,105,933	5,721,252	17.45	1.01	17.31	89.46
Male	2,188	2,188	2,206	37,946	6,098	3,154,992	4,136,081	17.34	1.01	17.20	69.35
Unknown	1	1	1	30	2	1,981	2,039	30.00	1.00	30.00	50.48
<i>NDCs only</i>											
183 day washout period											
Female	2,832	2,832	2,832	99,756	13,409	4,498,137	4,421,847	35.22	1.00	35.22	62.96
Male	1,721	1,721	1,721	59,703	8,044	3,455,494	3,152,538	34.69	1.00	34.69	49.80
Unknown	1	1	1	30	2	2,115	1,760	30.00	1.00	30.00	47.28
365 day washout period											
Female	2,050	2,050	2,050	68,304	7,875	4,107,519	5,727,775	33.32	1.00	33.32	49.91
Male	1,246	1,246	1,246	41,443	5,602	3,155,957	4,140,092	33.26	1.00	33.26	39.48
Unknown	1	1	1	30	2	1,982	2,040	30.00	1.00	30.00	50.45
<i>Procedure codes only</i>											
183 day washout period											
Female	3,175	3,175	3,203	3,203	3,203	4,498,163	4,421,814	1.01	1.01	1.00	70.58
Male	1,905	1,905	1,915	1,915	1,915	3,455,509	3,152,276	1.01	1.01	1.00	55.13
Unknown	0	0	0	0	0	2,114	1,759	0.00	0.00	0.00	0.00
365 day washout period											
Female	2,442	2,442	2,465	2,465	2,465	4,107,562	5,727,803	1.01	1.01	1.00	59.45
Male	1,450	1,450	1,458	1,458	1,458	3,155,913	4,139,878	1.01	1.01	1.00	45.95
Unknown	0	0	0	0	0	1,981	2,040	0.00	0.00	0.00	0.00

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
2003	29	77	2,228	292	6,777,112	3,287,321	76.83	2.66	28.94	0.43
2004	103	589	16,681	1,926	7,897,923	6,779,170	161.95	5.72	28.32	1.30
2005	201	1,528	26,028	3,530	8,236,050	7,039,146	129.49	7.60	17.03	2.44
2006	1,874	11,337	264,783	34,534	22,470,544	18,437,469	141.29	6.05	23.36	8.34
2007	2,264	13,367	286,917	38,238	25,864,037	20,274,117	126.73	5.90	21.46	8.75
2008	6,028	43,683	618,046	95,608	52,941,997	42,438,832	102.53	7.25	14.15	11.39
2009	5,920	43,467	620,234	92,715	51,225,531	41,742,543	104.77	7.34	14.27	11.56
2010	5,501	40,418	567,495	85,659	49,314,493	40,213,609	103.16	7.35	14.04	11.15
2011	5,469	41,147	544,368	83,684	47,992,398	39,400,309	99.54	7.52	13.23	11.40
2012	5,391	42,096	539,222	84,513	46,760,194	37,859,890	100.02	7.81	12.81	11.53
2013	4,178	16,872	208,581	33,284	39,540,672	14,396,433	49.92	4.04	12.36	10.57
365 day washout period										
2003	29	77	2,228	292	6,777,112	3,287,321	76.83	2.66	28.94	0.43
2004	103	589	16,681	1,926	7,897,923	6,779,170	161.95	5.72	28.32	1.30
2005	201	1,528	26,028	3,530	8,236,050	7,039,146	129.49	7.60	17.03	2.44
2006	1,874	11,337	264,783	34,534	22,470,544	18,437,469	141.29	6.05	23.36	8.34
2007	2,264	13,367	286,917	38,238	25,864,037	20,274,117	126.73	5.90	21.46	8.75
2008	6,028	43,683	618,046	95,608	52,941,997	42,438,832	102.53	7.25	14.15	11.39
2009	5,920	43,467	620,234	92,715	51,225,531	41,742,543	104.77	7.34	14.27	11.56
2010	5,501	40,418	567,495	85,659	49,314,493	40,213,609	103.16	7.35	14.04	11.15
2011	5,469	41,147	544,368	83,684	47,992,398	39,400,309	99.54	7.52	13.23	11.40
2012	5,391	42,096	539,222	84,513	46,760,194	37,859,890	100.02	7.81	12.81	11.53
2013	4,178	16,872	208,581	33,284	39,540,672	14,396,433	49.92	4.04	12.36	10.57

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria (Continued)										
<i>NDCs only</i>										
183 day washout period										
2003	29	77	2,228	292	6,777,112	3,287,321	76.83	2.66	28.94	0.43
2004	102	588	16,680	1,925	7,897,923	6,779,170	163.53	5.76	28.37	1.29
2005	130	871	25,371	2,873	8,236,050	7,039,146	195.16	6.70	29.13	1.58
2006	1,229	6,024	259,470	29,221	22,470,544	18,437,469	211.12	4.90	43.07	5.47
2007	1,540	7,077	280,627	31,948	25,864,037	20,274,117	182.23	4.60	39.65	5.95
2008	3,081	19,061	593,424	70,986	52,941,997	42,438,832	192.61	6.19	31.13	5.82
2009	3,084	19,539	596,306	68,787	51,225,531	41,742,543	193.35	6.34	30.52	6.02
2010	2,874	18,008	545,085	63,249	49,314,493	40,213,609	189.66	6.27	30.27	5.83
2011	2,746	17,437	520,658	59,974	47,992,398	39,400,309	189.61	6.35	29.86	5.72
2012	2,689	17,247	514,373	59,664	46,760,194	37,859,890	191.29	6.41	29.82	5.75
2013	2,052	6,618	198,327	23,030	39,540,672	14,396,433	96.65	3.23	29.97	5.19
365 day washout period										
2003	29	77	2,228	292	6,777,112	3,287,321	76.83	2.66	28.94	0.43
2004	102	588	16,680	1,925	7,897,923	6,779,170	163.53	5.76	28.37	1.29
2005	130	871	25,371	2,873	8,236,050	7,039,146	195.16	6.70	29.13	1.58
2006	1,229	6,024	259,470	29,221	22,470,544	18,437,469	211.12	4.90	43.07	5.47
2007	1,540	7,077	280,627	31,948	25,864,037	20,274,117	182.23	4.60	39.65	5.95
2008	3,081	19,061	593,424	70,986	52,941,997	42,438,832	192.61	6.19	31.13	5.82
2009	3,084	19,539	596,306	68,787	51,225,531	41,742,543	193.35	6.34	30.52	6.02
2010	2,874	18,008	545,085	63,249	49,314,493	40,213,609	189.66	6.27	30.27	5.83
2011	2,746	17,437	520,658	59,974	47,992,398	39,400,309	189.61	6.35	29.86	5.72
2012	2,689	17,247	514,373	59,664	46,760,194	37,859,890	191.29	6.41	29.82	5.75
2013	2,052	6,618	198,327	23,030	39,540,672	14,396,433	96.65	3.23	29.97	5.19

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria (Continued)										
<i>Procedure codes only</i>										
183 day washout period										
2003	0	0	0	0	6,777,112	3,287,321	0.00	0.00	0.00	0.00
2004	1	1	1	1	7,897,923	6,779,170	1.00	1.00	1.00	0.01
2005	90	657	657	657	8,236,050	7,039,146	7.30	7.30	1.00	1.09
2006	748	5,313	5,313	5,313	22,470,544	18,437,469	7.10	7.10	1.00	3.33
2007	858	6,290	6,290	6,290	25,864,037	20,274,117	7.33	7.33	1.00	3.32
2008	3,233	24,622	24,622	24,622	52,941,997	42,438,832	7.62	7.62	1.00	6.11
2009	3,215	23,928	23,928	23,928	51,225,531	41,742,543	7.44	7.44	1.00	6.28
2010	2,923	22,410	22,410	22,410	49,314,493	40,213,609	7.67	7.67	1.00	5.93
2011	3,029	23,710	23,710	23,710	47,992,398	39,400,309	7.83	7.83	1.00	6.31
2012	3,335	24,849	24,849	24,849	46,760,194	37,859,890	7.45	7.45	1.00	7.13
2013	2,489	10,254	10,254	10,254	39,540,672	14,396,433	4.12	4.12	1.00	6.29
365 day washout period										
2003	0	0	0	0	6,777,112	3,287,321	0.00	0.00	0.00	0.00
2004	1	1	1	1	7,897,923	6,779,170	1.00	1.00	1.00	0.01
2005	90	657	657	657	8,236,050	7,039,146	7.30	7.30	1.00	1.09
2006	748	5,313	5,313	5,313	22,470,544	18,437,469	7.10	7.10	1.00	3.33
2007	858	6,290	6,290	6,290	25,864,037	20,274,117	7.33	7.33	1.00	3.32
2008	3,233	24,622	24,622	24,622	52,941,997	42,438,832	7.62	7.62	1.00	6.11
2009	3,215	23,928	23,928	23,928	51,225,531	41,742,543	7.44	7.44	1.00	6.28
2010	2,923	22,410	22,410	22,410	49,314,493	40,213,609	7.67	7.67	1.00	5.93
2011	3,029	23,710	23,710	23,710	47,992,398	39,400,309	7.83	7.83	1.00	6.31
2012	3,335	24,849	24,849	24,849	46,760,194	37,859,890	7.45	7.45	1.00	7.13
2013	2,489	10,254	10,254	10,254	39,540,672	14,396,433	4.12	4.12	1.00	6.29

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma										
<i>NDCs and Procedure Codes</i>										
183 day washout period										
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
365 day washout period										
2003	29	77	2,228	292	409,694	160,239	76.83	2.66	28.94	7.08
2004	101	580	16,456	1,901	531,145	317,630	162.93	5.74	28.37	19.02
2005	197	1,510	25,518	3,471	597,467	366,777	129.53	7.66	16.90	32.97
2006	1,767	10,395	235,445	31,255	1,185,965	689,044	133.25	5.88	22.65	148.99
2007	2,209	12,990	275,997	37,055	1,551,507	919,159	124.94	5.88	21.25	142.38
2008	5,800	41,702	586,715	91,256	2,763,968	1,621,882	101.16	7.19	14.07	209.84
2009	5,811	42,872	608,209	91,153	3,299,402	1,974,468	104.67	7.38	14.19	176.12
2010	5,410	39,935	559,075	84,609	3,231,602	1,982,259	103.34	7.38	14.00	167.41
2011	5,368	40,627	535,526	82,534	3,148,088	1,931,920	99.76	7.57	13.18	170.52
2012	5,255	41,442	528,299	83,032	3,056,529	1,854,283	100.53	7.89	12.75	171.93
2013	4,061	16,454	202,288	32,430	2,262,078	676,418	49.81	4.05	12.29	179.53

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma (Continued)										
<i>NDCs only</i>										
183 day washout period										
2003	29	77	2,228	292	337,281	99,602	76.83	2.66	28.94	8.60
2004	100	578	16,427	1,896	449,205	202,447	164.27	5.78	28.42	22.26
2005	127	854	24,835	2,810	521,890	242,394	195.55	6.72	29.08	24.33
2006	1,138	5,346	230,259	26,197	1,091,215	502,029	202.34	4.70	43.07	104.29
2007	1,490	6,763	268,737	30,731	1,353,246	615,442	180.36	4.54	39.74	110.11
2008	2,949	18,064	562,832	67,589	2,564,215	1,183,462	190.86	6.13	31.16	115.01
2009	3,027	19,143	584,100	67,397	2,875,900	1,332,347	192.96	6.32	30.51	105.25
2010	2,815	17,730	536,357	62,378	2,828,285	1,321,891	190.54	6.30	30.25	99.53
2011	2,697	17,131	511,409	59,000	2,739,146	1,288,130	189.62	6.35	29.85	98.46
2012	2,627	16,879	503,207	58,437	2,646,583	1,237,183	191.55	6.43	29.81	99.26
2013	1,982	6,405	191,861	22,363	1,790,356	462,202	96.80	3.23	29.95	110.70
365 day washout period										
2003	29	77	2,228	292	409,694	160,239	76.83	2.66	28.94	7.08
2004	100	579	16,455	1,900	531,145	317,630	164.55	5.79	28.42	18.83
2005	127	855	24,863	2,816	597,467	366,777	195.77	6.73	29.08	21.26
2006	1,140	5,349	230,399	26,209	1,185,965	689,044	202.10	4.69	43.07	96.12
2007	1,494	6,778	269,785	30,843	1,551,507	919,159	180.58	4.54	39.80	96.29
2008	2,952	18,071	563,084	67,625	2,763,968	1,621,882	190.75	6.12	31.16	106.80
2009	3,031	19,155	584,492	67,436	3,299,402	1,974,468	192.84	6.32	30.51	91.87
2010	2,819	17,749	536,889	62,423	3,231,602	1,982,259	190.45	6.30	30.25	87.23
2011	2,698	17,145	511,801	59,044	3,148,088	1,931,920	189.70	6.35	29.85	85.70
2012	2,629	16,886	503,405	58,463	3,056,529	1,854,283	191.48	6.42	29.81	86.01
2013	1,986	6,414	192,113	22,381	2,262,078	676,418	96.73	3.23	29.95	87.80

Table 4a. Summary of Prevalent Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma (Continued)										
<i>Procedure codes only</i>										
183 day washout period										
2003	0	0	0	0	337,281	99,602	0.00	0.00	0.00	0.00
2004	1	1	1	1	449,205	202,447	1.00	1.00	1.00	0.22
2005	89	654	654	654	521,890	242,394	7.35	7.35	1.00	17.05
2006	718	5,042	5,042	5,042	1,091,215	502,029	7.02	7.02	1.00	65.80
2007	846	6,206	6,206	6,206	1,353,246	615,442	7.34	7.34	1.00	62.52
2008	3,113	23,618	23,618	23,618	2,564,215	1,183,462	7.59	7.59	1.00	121.40
2009	3,145	23,700	23,700	23,700	2,875,900	1,332,347	7.54	7.54	1.00	109.36
2010	2,881	22,173	22,173	22,173	2,828,285	1,321,891	7.70	7.70	1.00	101.86
2011	2,960	23,464	23,464	23,464	2,739,146	1,288,130	7.93	7.93	1.00	108.06
2012	3,237	24,495	24,495	24,495	2,646,583	1,237,183	7.57	7.57	1.00	122.31
2013	2,421	10,010	10,010	10,010	1,790,356	462,202	4.13	4.13	1.00	135.22
365 day washout period										
2003	0	0	0	0	409,694	160,239	0.00	0.00	0.00	0.00
2004	1	1	1	1	531,145	317,630	1.00	1.00	1.00	0.19
2005	89	655	655	655	597,467	366,777	7.36	7.36	1.00	14.90
2006	719	5,046	5,046	5,046	1,185,965	689,044	7.02	7.02	1.00	60.63
2007	848	6,212	6,212	6,212	1,551,507	919,159	7.33	7.33	1.00	54.66
2008	3,117	23,631	23,631	23,631	2,763,968	1,621,882	7.58	7.58	1.00	112.77
2009	3,152	23,717	23,717	23,717	3,299,402	1,974,468	7.52	7.52	1.00	95.53
2010	2,883	22,186	22,186	22,186	3,231,602	1,982,259	7.70	7.70	1.00	89.21
2011	2,965	23,472	23,472	23,472	3,148,088	1,931,920	7.92	7.92	1.00	94.18
2012	3,245	24,536	24,536	24,536	3,056,529	1,854,283	7.56	7.56	1.00	106.17
2013	2,426	10,030	10,030	10,030	2,262,078	676,418	4.13	4.13	1.00	107.25

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
2003	25	25	25	764	100	6,318,111	3,005,766	30.56	1.00	30.56	0.40
2004	59	59	59	1,625	198	7,224,766	5,867,222	27.54	1.00	27.54	0.82
2005	99	99	99	1,600	234	7,484,254	6,257,169	16.16	1.00	16.16	1.32
2006	417	417	418	14,430	1,802	18,720,089	11,297,900	34.60	1.00	34.52	2.23
2007	642	642	649	24,085	3,171	22,567,324	16,444,252	37.52	1.01	37.11	2.84
2008	1,261	1,261	1,276	22,471	5,149	43,820,626	27,674,325	17.82	1.01	17.61	2.88
2009	1,625	1,625	1,640	23,999	3,765	45,702,241	35,793,169	14.77	1.01	14.63	3.56
2010	1,357	1,357	1,366	20,164	3,113	43,879,358	34,484,290	14.86	1.01	14.76	3.09
2011	1,348	1,348	1,358	20,842	3,153	42,693,384	33,895,705	15.46	1.01	15.35	3.16
2012	1,294	1,294	1,295	20,115	3,058	41,608,958	32,684,011	15.54	1.00	15.53	3.11
2013	496	496	497	8,540	1,231	33,139,230	12,043,175	17.22	1.00	17.18	1.50
365 day washout period											
2003	23	23	23	708	95	5,582,673	2,730,785	30.78	1.00	30.78	0.41
2004	51	51	51	1,399	168	6,498,067	5,175,035	27.43	1.00	27.43	0.78
2005	79	79	79	1,086	155	6,412,197	5,598,035	13.75	1.00	13.75	1.23
2006	88	88	88	1,351	201	6,628,828	5,791,127	15.35	1.00	15.35	1.33
2007	470	470	477	17,159	2,276	16,867,418	14,244,820	36.51	1.01	35.97	2.79
2008	523	523	532	10,287	1,433	36,277,380	15,693,192	19.67	1.02	19.34	1.44
2009	1,289	1,289	1,302	18,404	2,910	37,047,853	30,628,910	14.28	1.01	14.14	3.48
2010	1,077	1,077	1,085	15,475	2,409	35,563,042	29,827,096	14.37	1.01	14.26	3.03
2011	1,115	1,115	1,124	17,154	2,539	34,880,144	29,329,922	15.38	1.01	15.26	3.20
2012	1,043	1,043	1,044	16,195	2,454	36,966,729	28,381,882	15.53	1.00	15.51	2.82
2013	420	420	421	6,883	969	29,244,622	10,712,166	16.39	1.00	16.35	1.44

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria (Continued)											
<i>NDCs only</i>											
183 day washout period											
2003	25	25	25	764	100	6,318,111	3,005,766	30.56	1.00	30.56	0.40
2004	58	58	58	1,624	197	7,224,766	5,867,222	28.00	1.00	28.00	0.80
2005	47	47	47	1,602	188	7,484,261	6,257,204	34.09	1.00	34.09	0.63
2006	284	284	284	15,064	1,737	18,720,518	11,298,170	53.04	1.00	53.04	1.52
2007	464	464	464	25,361	3,130	22,567,828	16,444,785	54.66	1.00	54.66	2.06
2008	707	707	707	23,614	4,719	43,822,555	27,675,743	33.40	1.00	33.40	1.61
2009	855	855	855	25,735	3,329	45,704,327	35,795,434	30.10	1.00	30.10	1.87
2010	687	687	687	21,185	2,597	43,881,587	34,486,569	30.84	1.00	30.84	1.57
2011	718	718	718	21,880	2,666	42,695,884	33,898,185	30.47	1.00	30.47	1.68
2012	663	663	663	21,665	2,657	41,611,632	32,686,579	32.68	1.00	32.68	1.59
2013	280	280	280	9,268	1,112	33,141,748	12,044,190	33.10	1.00	33.10	0.84
365 day washout period											
2003	23	23	23	708	95	5,582,673	2,730,785	30.78	1.00	30.78	0.41
2004	50	50	50	1,398	167	6,498,067	5,175,035	27.96	1.00	27.96	0.77
2005	35	35	35	1,096	117	6,412,203	5,598,066	31.31	1.00	31.31	0.55
2006	48	48	48	1,365	165	6,628,888	5,791,191	28.44	1.00	28.44	0.72
2007	351	351	351	18,465	2,289	16,867,906	14,245,344	52.61	1.00	52.61	2.08
2008	326	326	326	11,087	1,309	36,279,588	15,693,793	34.01	1.00	34.01	0.90
2009	678	678	678	20,112	2,619	37,049,866	30,631,104	29.66	1.00	29.66	1.83
2010	545	545	545	16,554	2,030	35,565,011	29,829,180	30.37	1.00	30.37	1.53
2011	598	598	598	17,952	2,124	34,882,290	29,332,131	30.02	1.00	30.02	1.71
2012	534	534	534	17,539	2,130	36,969,250	28,384,182	32.84	1.00	32.84	1.44
2013	228	228	228	7,392	854	29,246,911	10,713,094	32.42	1.00	32.42	0.78

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
No Pre-existing Condition Criteria (Continued)											
<i>Procedure codes only</i>											
183 day washout period											
2003	0	0	0	0	0	6,318,115	3,005,772	0.00	0.00	0.00	0.00
2004	1	1	1	1	1	7,224,806	5,867,279	1.00	1.00	1.00	0.01
2005	75	75	75	75	75	7,484,349	6,257,257	1.00	1.00	1.00	1.00
2006	180	180	181	181	181	18,720,807	11,298,374	1.01	1.01	1.00	0.96
2007	280	280	285	285	285	22,568,297	16,445,192	1.02	1.02	1.00	1.24
2008	714	714	727	727	727	43,822,694	27,676,027	1.02	1.02	1.00	1.63
2009	1,047	1,047	1,057	1,057	1,057	45,704,483	35,795,445	1.01	1.01	1.00	2.29
2010	860	860	864	864	864	43,881,682	34,486,528	1.00	1.00	1.00	1.96
2011	849	849	856	856	856	42,695,715	33,897,924	1.01	1.01	1.00	1.99
2012	1,074	1,074	1,074	1,074	1,074	41,611,250	32,686,139	1.00	1.00	1.00	2.58
2013	354	354	354	354	354	33,141,149	12,043,938	1.00	1.00	1.00	1.07
365 day washout period											
2003	0	0	0	0	0	5,582,674	2,730,789	0.00	0.00	0.00	0.00
2004	1	1	1	1	1	6,498,103	5,175,086	1.00	1.00	1.00	0.02
2005	65	65	65	65	65	6,412,286	5,598,115	1.00	1.00	1.00	1.01
2006	51	51	51	51	51	6,628,926	5,791,231	1.00	1.00	1.00	0.77
2007	219	219	224	224	224	16,868,229	14,245,733	1.02	1.02	1.00	1.30
2008	280	280	288	288	288	36,279,570	15,694,250	1.03	1.03	1.00	0.77
2009	859	859	867	867	867	37,049,885	30,631,013	1.01	1.01	1.00	2.32
2010	700	700	704	704	704	35,565,061	29,829,096	1.01	1.01	1.00	1.97
2011	714	714	721	721	721	34,882,137	29,331,914	1.01	1.01	1.00	2.05
2012	904	904	904	904	904	36,968,858	28,383,755	1.00	1.00	1.00	2.45
2013	310	310	310	310	310	29,246,323	10,712,842	1.00	1.00	1.00	1.06

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma											
<i>NDCs and Procedure Codes</i>											
183 day washout period											
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
365 day washout period											
2003	23	23	23	708	95	366,881	142,711	30.78	1.00	30.78	6.27
2004	51	51	51	1,399	168	486,103	274,854	27.43	1.00	27.43	10.49
2005	77	77	77	974	151	526,481	317,681	12.65	1.00	12.65	14.63
2006	84	84	84	1,237	187	582,327	355,183	14.73	1.00	14.73	14.42
2007	454	454	461	16,815	2,224	1,267,741	763,506	37.04	1.02	36.48	35.81
2008	498	498	507	10,026	1,381	2,321,464	865,082	20.13	1.02	19.78	21.45
2009	1,221	1,221	1,234	17,792	2,782	2,807,835	1,655,169	14.57	1.01	14.42	43.49
2010	1,034	1,034	1,041	15,074	2,340	2,764,533	1,682,165	14.58	1.01	14.48	37.40
2011	1,068	1,068	1,077	16,727	2,469	2,701,638	1,639,256	15.66	1.01	15.53	39.53
2012	973	973	974	15,020	2,291	2,777,536	1,581,098	15.44	1.00	15.42	35.03
2013	379	379	380	6,294	899	1,947,061	582,668	16.61	1.00	16.56	19.47

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma (Continued)											
<i>NDCs only</i>											
183 day washout period											
2003	25	25	25	764	100	327,797	94,619	30.56	1.00	30.56	7.63
2004	57	57	57	1,596	193	435,347	187,414	28.00	1.00	28.00	13.09
2005	45	45	45	1,490	184	504,764	226,591	33.11	1.00	33.11	8.92
2006	257	257	257	13,696	1,572	1,028,006	383,719	53.29	1.00	53.29	25.00
2007	445	445	445	24,227	2,979	1,296,999	550,115	54.44	1.00	54.44	34.31
2008	674	674	674	22,721	4,607	2,406,955	923,907	33.71	1.00	33.71	28.00
2009	826	826	826	24,753	3,204	2,776,551	1,228,944	29.97	1.00	29.97	29.75
2010	655	655	655	20,283	2,470	2,733,925	1,222,277	30.97	1.00	30.97	23.96
2011	694	694	694	21,262	2,600	2,643,084	1,190,823	30.64	1.00	30.64	26.26
2012	622	622	622	20,247	2,509	2,554,677	1,146,175	32.55	1.00	32.55	24.35
2013	254	254	254	8,450	1,037	1,641,281	421,562	33.27	1.00	33.27	15.48
365 day washout period											
2003	23	23	23	708	95	366,881	142,711	30.78	1.00	30.78	6.27
2004	50	50	50	1,398	167	486,103	274,854	27.96	1.00	27.96	10.29
2005	33	33	33	984	113	526,487	317,712	29.82	1.00	29.82	6.27
2006	44	44	44	1,251	151	582,387	355,247	28.43	1.00	28.43	7.56
2007	343	343	343	18,129	2,245	1,268,242	764,026	52.85	1.00	52.85	27.05
2008	317	317	317	10,842	1,273	2,323,669	865,674	34.20	1.00	34.20	13.64
2009	660	660	660	19,550	2,541	2,809,870	1,657,324	29.62	1.00	29.62	23.49
2010	532	532	532	16,184	1,992	2,766,478	1,684,181	30.42	1.00	30.42	19.23
2011	583	583	583	17,530	2,086	2,703,732	1,641,372	30.07	1.00	30.07	21.56
2012	502	502	502	16,375	2,009	2,779,974	1,583,269	32.62	1.00	32.62	18.06
2013	210	210	210	6,826	807	1,949,235	583,537	32.50	1.00	32.50	10.77

Table 4b. Summary of Incident Omalizumab Use in the MSDD between June 23, 2003 and May 31, 2013, by Pre-existing Condition Criteria, Code Type, Washout Period, 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
Pre-existing Asthma (Continued)											
<i>Procedure codes only</i>											
183 day washout period											
2003	0	0	0	0	0	327,801	94,624	0.00	0.00	0.00	0.00
2004	1	1	1	1	1	435,386	187,469	1.00	1.00	1.00	0.23
2005	75	75	75	75	75	504,849	226,638	1.00	1.00	1.00	14.86
2006	163	163	164	164	164	1,028,267	383,887	1.01	1.01	1.00	15.85
2007	265	265	270	270	270	1,297,442	550,466	1.02	1.02	1.00	20.42
2008	661	661	673	673	673	2,407,002	924,106	1.02	1.02	1.00	27.46
2009	974	974	984	984	984	2,776,626	1,228,877	1.01	1.01	1.00	35.08
2010	811	811	814	814	814	2,734,004	1,222,191	1.00	1.00	1.00	29.66
2011	803	803	810	810	810	2,642,898	1,190,530	1.01	1.01	1.00	30.38
2012	1,005	1,005	1,005	1,005	1,005	2,554,317	1,145,743	1.00	1.00	1.00	39.35
2013	322	322	322	322	322	1,640,713	421,316	1.00	1.00	1.00	19.63
365 day washout period											
2003	0	0	0	0	0	366,882	142,716	0.00	0.00	0.00	0.00
2004	1	1	1	1	1	486,139	274,904	1.00	1.00	1.00	0.21
2005	65	65	65	65	65	526,570	317,759	1.00	1.00	1.00	12.34
2006	51	51	51	51	51	582,421	355,282	1.00	1.00	1.00	8.76
2007	211	211	216	216	216	1,268,535	764,384	1.02	1.02	1.00	16.63
2008	264	264	272	272	272	2,323,611	866,102	1.03	1.03	1.00	11.36
2009	809	809	817	817	817	2,809,840	1,657,200	1.01	1.01	1.00	28.79
2010	669	669	672	672	672	2,766,504	1,684,080	1.00	1.00	1.00	24.18
2011	678	678	685	685	685	2,703,577	1,641,147	1.01	1.01	1.00	25.08
2012	860	860	860	860	860	2,779,592	1,582,852	1.00	1.00	1.00	30.94
2013	284	284	284	284	284	1,948,671	583,295	1.00	1.00	1.00	14.57

Appendix A. HCPCS for Exposure Included in this Request

Description	HCPCS
OMALIZUMAB	J2357

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

Description	Diagnosis Code
Asthma	493*