Disclaimer

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

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

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

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

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Overview for Request MSY4_MPR57_V1

Request ID: msy4_mpr57_v1, report 1 of 2

Request Description: This report estimates the rate of hospital re-admission with Clostridium difficile (C. difficile) infection (identified using International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] code 008.45) following treatment with oral vancomycin, fidaxomicin, or metronidazole.

Sentinel Modular Program Tool Used: Modular Program #3 (MP3)

Data Source: Data from January 1, 2000 to December 31, 2012 from 18 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD) were utilized for the two reports that encompass this request. This request was distributed to Data Partners on August 27, 2013. See Appendix A for a list of the dates of available data for each Data Partner. Report 1 has a query period of May 1, 2011 to December 31, 2012. Report 2 has a query period of January 1, 2000 to December 31, 2012. Please see Appendix B for details into the exact parameters used in this request.

Study Design: This request identifies new users of oral vancomycin, fidaxomicin, or metronidazole who had an inpatient C. difficile diagnosis prior to treatment dispensing (i.e. a "pre-existing condition" of C. difficile in the 45 or 90 days prior); a subsequent inpatient C. difficile diagnosis is the outcome/event of interest. The number of users, dispensings, total days supplied, eligible members, member-days, and other counts are reported. Eight scenarios were examined; scenarios 1-6 are in this report: (1) vancomycin, 45 day look-back for prior C. difficile, (2) vancomycin, 90 day look-back, (3) fidaxomicin, 45 day look-back, (4) fidaxomicin, 90 day look-back, (5) metronidazole, 45 day look-back, and (6) metronidazole, 90 day look-back.

Cohort Eligibility Criteria: Patients in the following age groups were included in the cohort: 0-<20, 20-<45, 45-<65, 65-<75, 75-<85, and 85+ years.

Limitation: Algorithms to define exposures are imperfect and, therefore, they may be misclassified.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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Glossary of Terms in Modular Program 3*

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

Eligible Members - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing

Member-Days - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be

Minimum Episode Duration - specifies a minimum number of days in length of the epsiode for it to be considered

New Episodes - new treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive

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

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Total Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Washout Period (drug/exposure) -** number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) -** number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Type (drug/exposure)- *Minimum washout type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple washout types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will

Washout Type (event/outcome)- *Minimum washout type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple washout type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple*

*all terms may not be used in this report

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

Table 1: Summary of Fidaxomicin, Metronidazole, and Vancomycin Use and Clostridium Difficile in the Mini-Sentinel Distributed Database (MSDD) between May 1, 2011 and December 31, 2012, by Drug Product and Pre-Existing Condition Lookback Period

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Fidaxomicin													
45-Day Lookback Period	304	305	363	3,223	29	51	37,376	4,899	8.13	10.60	1.19	8.88	1,787.01
90-Day Lookback Period	387	389	468	4,192	37	59	40,008	8,574	9.67	10.83	1.21	8.96	1,601.62
Metronidazole													
45-Day Lookback Period	8,552	8,576	9,797	105,130	815	1,495	30,471	3,093	280.66	12.29	1.15	10.73	1,834.72
90-Day Lookback Period	9,014	9,043	10,406	112,290	861	1,582	32,172	5,154	280.18	12.46	1.15	10.79	1,836.49
Vancomycin													
45-Day Lookback Period	4,436	4,462	5,743	74,347	461	839	36,079	4,264	122.95	16.76	1.29	12.95	1,820.79
90-Day Lookback Period	4,752	4,781	6,172	81,616	498	884	38,326	7,316	123.99	17.18	1.30	13.22	1,775.10

The pre-exisiting condition is an inpatient C. difficile diagnosis in the 45 or 90 days prior to treatment dispensing.
A subsequent inpatient C. difficile diagnosis, after treatment initiation, is the outcome/event of interest.

Table 2: Summary of Fidaxomicin, Metronidazole, and Vancomycin Use and Clostridium Difficile in the Mini-Sentinel Distributed Database (MSDD) between May 1, 2011 and December 31, 2012, by Drug Product, Pre-Existing Condition Lookback Period, and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Fidaxomicin (Lookback Period for Pre-Existing Condition = 45 Days)													
0 to 19 Years	1	1	3	60	0	0	1,204	156	0.83	60.00	3.00	20.00	0.00
20 to 44 Years	39	39	44	409	4	7	3,539	442	11.02	10.49	1.13	9.30	1,830.17
45 to 64 Years	107	108	131	1,226	10	19	9,851	1,261	10.86	11.46	1.22	9.36	1,861.52
65 to 74 Years	66	66	76	659	6	12	7,786	1,031	8.48	9.98	1.15	8.67	2,020.75
75 to 84 Years	61	61	77	591	5	10	9,278	1,227	6.57	9.69	1.26	7.68	1,847.50
85+ Years	30	30	32	278	3	3	6,152	782	4.88	9.27	1.07	8.69	1,030.81
Fidaxomicin (Lookback Period for Pre-Existing Condition = 90 Days)													
0 to 19 Years	4	4	6	94	1	0	1,353	300	2.96	23.50	1.50	15.67	0.00
20 to 44 Years	51	51	56	532	5	9	3,883	831	13.13	10.43	1.10	9.50	1,869.88
45 to 64 Years	143	144	172	1,641	14	21	10,645	2,291	13.43	11.48	1.20	9.54	1,512.57
65 to 74 Years	73	73	84	729	7	14	8,406	1,781	8.68	9.99	1.15	8.68	2,116.51
75 to 84 Years	80	80	109	834	7	12	9,863	2,067	8.11	10.43	1.36	7.65	1,645.89
85+ Years	37	37	41	362	4	3	6,540	1,304	5.66	9.78	1.11	8.83	816.51
Metronidazole (Lookback Period for Pre-Existing Condition = 45 Days)													
0 to 19 Years	412	413	455	4,841	41	54	941	77	437.83	11.75	1.10	10.64	1,304.12
20 to 44 Years	1,142	1,142	1,250	13,924	116	114	2,575	211	443.50	12.19	1.09	11.14	983.15
45 to 64 Years	2,741	2,755	3,112	33,669	270	408	7,621	695	359.66	12.28	1.14	10.82	1,510.64
65 to 74 Years	1,752	1,756	2,013	21,664	162	343	6,380	666	274.61	12.37	1.15	10.76	2,111.41
75 to 84 Years	1,624	1,627	1,925	20,114	148	353	7,883	862	206.01	12.39	1.19	10.45	2,379.06
85+ Years	883	883	1,042	10,918	77	223	5,368	582	164.49	12.36	1.18	10.48	2,912.60

Table 2: Summary of Fidaxomicin, Metronidazole, and Vancomycin Use and Clostridium Difficile in the Mini-Sentinel Distributed Database (MSDD) between May 1, 2011 and December 31, 2012, by Drug Product, Pre-Existing Condition Lookback Period, and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 1K Years at Risk
Metronidazole (Lookback Period for Pre-Existing Condition = 90 Days)													
0 to 19 Years	424	425	472	5,112	43	57	1,027	145	412.85	12.06	1.11	10.83	1,336.71
20 to 44 Years	1,178	1,178	1,295	14,395	119	119	2,743	375	429.46	12.22	1.10	11.12	996.67
45 to 64 Years	2,866	2,880	3,271	35,805	283	424	8,078	1,194	354.79	12.49	1.14	10.95	1,496.62
65 to 74 Years	1,843	1,848	2,119	22,842	171	364	6,785	1,097	271.63	12.39	1.15	10.78	2,129.67
75 to 84 Years	1,734	1,739	2,072	21,788	159	376	8,314	1,397	208.56	12.57	1.19	10.52	2,361.80
85+ Years	971	973	1,177	12,348	86	242	5,673	945	171.16	12.72	1.21	10.49	2,815.16
Vancomycin (Lookback Period for Pre-Existing Condition = 45 Days)													
0 to 19 Years	115	115	151	1,827	13	16	1,153	136	99.74	15.89	1.31	12.10	1,274.31
20 to 44 Years	691	697	885	10,887	74	98	3,318	346	208.26	15.76	1.28	12.30	1,331.69
45 to 64 Years	1,711	1,717	2,203	27,488	181	286	9,382	1,027	182.37	16.07	1.29	12.48	1,580.59
65 to 74 Years	771	773	981	12,928	77	162	7,562	917	101.96	16.77	1.27	13.18	2,090.83
75 to 84 Years	748	756	1,010	13,531	75	178	9,032	1,117	82.82	18.09	1.35	13.40	2,366.92
85+ Years	401	404	513	7,686	41	99	6,016	721	66.66	19.17	1.28	14.98	2,413.87
Vancomycin (Lookback Period for Pre-Existing Condition = 90 Days)													
0 to 19 Years	124	124	164	2,037	14	17	1,292	260	95.98	16.43	1.32	12.42	1,245.34
20 to 44 Years	718	725	927	11,418	77	101	3,583	638	200.39	15.90	1.29	12.32	1,315.68
45 to 64 Years	1,804	1,811	2,336	29,896	193	298	10,003	1,819	180.35	16.57	1.29	12.80	1,544.35
65 to 74 Years	821	824	1,046	13,912	83	167	8,108	1,565	101.26	16.95	1.27	13.30	2,004.16
75 to 84 Years	832	840	1,116	15,009	84	193	9,564	1,850	86.99	18.04	1.34	13.45	2,302.72
85+ Years	454	457	583	9,344	47	108	6,374	1,184	71.23	20.58	1.28	16.03	2,274.52

The pre-exisiting condition is an inpatient C. difficile diagnosis in the 45 or 90 days prior to treatment dispensing.
A subsequent inpatient C. difficile diagnosis, after treatment initiation, is the outcome/event of interest.

Table 3: Summary of Fidaxomicin, Metronidazole, and Vancomycin Use and Clostridium Difficile in the Mini-Sentinel Distributed Database (MSDD) between May 1, 2011 and December 31, 2012, by Drug Product, Pre-Existing Condition Lookback Period, and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied / User	Dispensings / User	Days Supplied / Dispensing	Events / 1K Years at Risk
Fidaxomicin (Lookback Period for Pre-Existing Condition = 45 Days)													
Female	208	208	239	2,184	20	32	21,866	2,877	9.51	10.50	1.15	9.14	1,631.95
Male	96	97	124	1,039	9	19	15,510	2,022	6.19	10.82	1.29	8.38	2,127.45
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---
Fidaxomicin (Lookback Period for Pre-Existing Condition = 90 Days)													
Female	266	266	316	2,858	25	38	23,377	5,063	11.38	10.74	1.19	9.04	1,503.90
Male	121	123	152	1,334	12	21	16,631	3,512	7.28	11.02	1.26	8.78	1,815.01
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---
Metronidazole (Lookback Period for Pre-Existing Condition = 45 Days)													
Female	5,062	5,078	5,827	62,460	484	894	17,510	1,765	289.09	12.34	1.15	10.72	1,845.49
Male	3,490	3,498	3,970	42,670	330	601	12,961	1,328	269.27	12.23	1.14	10.75	1,818.94
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---
Metronidazole (Lookback Period for Pre-Existing Condition = 90 Days)													
Female	5,317	5,337	6,158	66,154	510	945	18,469	2,963	287.89	12.44	1.16	10.74	1,853.54
Male	3,697	3,706	4,248	46,136	352	637	13,703	2,190	269.79	12.48	1.15	10.86	1,811.76
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---
Vancomycin (Lookback Period for Pre-Existing Condition = 45 Days)													
Female	2,789	2,808	3,688	47,992	289	550	21,062	2,477	132.42	17.21	1.32	13.01	1,901.62
Male	1,647	1,654	2,055	26,355	172	289	15,017	1,787	109.68	16.00	1.25	12.82	1,684.52
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---
Vancomycin (Lookback Period for Pre-Existing Condition = 90 Days)													
Female	2,967	2,988	3,938	52,386	311	572	22,343	4,274	132.79	17.66	1.33	13.30	1,839.60
Male	1,785	1,793	2,234	29,230	187	312	15,983	3,042	111.68	16.38	1.25	13.08	1,667.88
Unknown	0	0	0	0	0	0	0	0	---	---	---	---	---

The pre-exisiting condition is an inpatient C. difficile diagnosis in the 45 or 90 days prior to treatment dispensing.
A subsequent inpatient C. difficile diagnosis, after treatment initiation, is the outcome/event of interest.

Table 4: Summary of Fidaxomicin, Metronidazole, and Vancomycin Use and Clostridium Difficile in the Mini-Sentinel Distributed Database (MSDD) between May 1, 2011 and December 31, 2012, by Drug Product, Pre-Existing Condition Lookback Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied / User	Dispensings / User	Days Supplied / Dispensing	Events / 1K Years at Risk
Fidaxomicin (Lookback Period for Pre-Existing Condition = 45 Days)													
2011	64	64	75	758	6	14	17,730	2,056	3.61	11.84	1.17	10.11	2,284.85
2012	241	241	288	2,465	22	37	23,163	2,843	10.40	10.23	1.20	8.56	1,650.90
Fidaxomicin (Lookback Period for Pre-Existing Condition = 90 Days)													
2011	89	89	103	1,048	8	18	20,035	3,610	4.44	11.78	1.16	10.17	2,131.12
2012	300	300	365	3,144	28	41	25,436	4,964	11.79	10.48	1.22	8.61	1,444.09
Metronidazole (Lookback Period for Pre-Existing Condition = 45 Days)													
2011	3,642	3,642	4,170	44,788	354	606	14,040	1,285	259.40	12.30	1.14	10.74	1,710.93
2012	4,930	4,934	5,627	60,342	461	889	18,686	1,808	263.83	12.24	1.14	10.72	1,929.91
Metronidazole (Lookback Period for Pre-Existing Condition = 90 Days)													
2011	3,818	3,819	4,415	47,831	373	634	15,438	2,144	247.31	12.53	1.16	10.83	1,699.81
2012	5,218	5,224	5,991	64,459	488	948	20,106	3,010	259.52	12.35	1.15	10.76	1,940.86
Vancomycin (Lookback Period for Pre-Existing Condition = 45 Days)													
2011	1,886	1,886	2,452	31,570	201	339	16,889	1,779	111.67	16.74	1.30	12.88	1,683.23
2012	2,573	2,576	3,291	42,777	259	500	22,302	2,485	115.37	16.63	1.28	13.00	1,927.60
Vancomycin (Lookback Period for Pre-Existing Condition = 90 Days)													
2011	2,008	2,008	2,618	34,303	217	354	18,859	3,052	106.47	17.08	1.30	13.10	1,632.04
2012	2,770	2,773	3,554	47,313	281	530	24,246	4,264	114.25	17.08	1.28	13.31	1,885.48

The pre-exisiting condition is an inpatient C. difficile diagnosis in the 45 or 90 days prior to treatment dispensing.
A subsequent inpatient C. difficile diagnosis, after treatment initiation, is the outcome/event of interest.

Appendix A: Available Data in the Sentinel Distributed Database (SDD) for Each Data Partner as of Request Send Date (August 27, 2013)

Data Partner ID	Start Date	End Date
DP001	1/2/2008	11/30/2012
DP002	1/2/2006	3/30/2013
DP003	1/31/2004	4/30/2013
DP004	1/1/2000	4/30/2012
DP005	1/2/2000	12/31/2011
DP006	1/1/2000	12/31/2011
DP007	1/2/2000	6/30/2012
DP008	1/2/2000	6/30/2012
DP009	6/2/2007	10/31/2012
DP010	1/2/2000	3/31/2013
DP011	1/2/2000	5/31/2013
DP012	1/2/2005	12/31/2012
DP013	1/31/2000	12/31/2012
DP014	1/31/2000	5/31/2013
DP015	1/2/2008	9/30/2012
DP016	1/2/2000	12/31/2012
DP017	1/1/2000	12/31/2012
DP018	1/1/2000	12/31/2012

Appendix B: Modular Program Specifications MSY4_MPR57_v1

Modular Program #3 was used to estimate the rate of hospital re-admission with Clostridium difficile (C. difficile) infection (identified using International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] code 008.45) following treatment with oral vancomycin, fidaxomicin, or metronidazole. In total, eight different scenarios were examined in this request with differing exposures of interest, blackout periods, and inclusion/exclusion criteria. This report contains results from scenarios 1 through 6, where the query period was from May 1, 2011 to December 31, 2012. A second report (MS_Brief_Report_MSY4_MPR57_r2.xls) contains results from scenarios 7 and 8, where the query period was from January 1, 2000 to December, 2012. See below for a description of each of these scenarios.

Enrollment Gap	45 Days
Age Groups	0-<20, 20-<45, 45-<65, 65-<75, 75-<85, and 85+ years
Query Period	Scenarios 1-6: May 1, 2011 - December 31, 2012
	Scenarios 7-8 : January 1, 2000 - December 31, 2012

	Drug/Exposure								Pre-Existing Condition					Event/Outcome						
Scenario	Incident exposure	Incident w/ respect to:	Washout (days)	Washout Type	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting	Event/ Outcome	Care Setting	Incident w/ respect to:	Incident Only Care Setting	Washout (days)	Washout Type	Blackout Period
1	Vancomycin	Vancomycin	183	MULT	10	30	0	0	C. Diff infection	Include	-45	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
2	Vancomycin	Vancomycin	183	MULT	10	30	0	0	C. Diff infection	Include	-90	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
3	Fidaxomicin	Fidaxomicin	183	MULT	10	30	0	0	C. Diff infection	Include	-45	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
4	Fidaxomicin	Fidaxomicin	183	MULT	10	30	0	0	C. Diff infection	Include	-90	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
5	Metronidazole	Metronidazole	183	MULT	10	30	0	0	C. Diff infection	Include	-45	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
6	Metronidazole	Metronidazole	183	MULT	10	30	0	0	C. Diff infection	Include	-90	-1	IP*	C. Diff infection	IP*	C. Diff infection	IP*	0	MULT	0
7	*Vancomycin*	*Vancomycin*	*183*	*MULT*	*10*	*30*	*0*	*0*	*C. Diff infection*	*Include*	*-45*	*-1*	*IP**	*C. Diff infection*	*IP**	*C. Diff infection*	*IP**	*0*	*MULT*	*0*
8	*Metronidazole*	*Metronidazole*	*183*	*MULT*	*10*	*30*	*0*	*0*	*C. Diff infection*	*Include*	*-45*	*-1*	*IP**	*C. Diff infection*	*IP**	*C. Diff infection*	*IP**	*0*	*MULT*	*0*

National Drug Codes (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
Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight
Current Procedural Terminology (CPT) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight