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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 ID cder_mpl1r_wp047_nsdp_v01

Request ID: cder_mpl1r_wp047_nsdp_v01

Report Description: This report investigated episode length and cumulative days' supply of teriparatide therapy.

Sentinel Modular Program Tool Used: Modular Program 8, version 2.6.

Data Source: Data from July 1, 2009 to June 30, 2016 from 16 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on November 14, 2016. Please refer to Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: This request was designed to calculate the number of episodes by length and cumulative days of supply of teriparatide therapy. Both episodes and cumulative days supplied were calculated by age group.

Exposure of Interest: The exposure of interest was teriparatide, which was defined using a National Drug Code (NDC).

Cohort Eligibility Criteria: Patients were required to be enrolled in both drug and medical coverage for at least 90 days before their index date, during which gaps in coverage up to 45 days were allowed. Index was defined as a new dispensing of teriparatide without a previous dispensing in the prior 90 days. A patient's minimum episode duration was one day and a gap of 15 days between episodes would be bridged and considered one episode. The following age groups were included: 19-60, 65+ years.

Please see Appendix B for a list of parameters used in this request.

Limitations: Algorithms used to define events are imperfect; thus, it is possible that there may be misclassification.

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

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Glossary of Terms in Modular Program 8*

Age Stratifications - Age group categories for reporting. Specifying this parameter will (1) restrict to certain age groups and (2) specify how age groups will be stratified in the result tables. For example, to have results stratified by 20 year increments for members 40-99 years of age, AGESTRAT=40-59 60-79 80-99 would be entered.

Approval Date - Approval date of new molecular entity of interest.

Days of Supply Groups - Days of supply categories for reporting. This parameter will specify how claim days of supply will be stratified in result tables examining distribution of days supplied. For example, to have results stratified by 15 days increments for claims with 15-60 days of supply, DISPDAYSUPSTRAT=15-29 30-44 45-60 would be entered.

Enrollment Gap - Sets the number of days that will be bridged between two consecutive enrollment periods to create a "continuously enrolled" period. For example, if ENROLGAP=30 and a member is eligible for medical and drug coverage in periods 1/1/2007-3/27/2007 and 4/1/2007-12/21/2007 (i.e., a 4-day gap between two consecutive enrollment episodes), the member will be considered continuously enrolled from 1/1/2007 to 12/21/2007. Any gaps in enrollment greater than 30 days will result in a new enrollment period, and all the days in the gap will be considered un-enrolled. A recommended enrollment gap is 45 days.

Episode Gap - For a given claim, if EPISODEGAPTYPE is Fixed (F), a gap of more than EPISODEGAP days between the claim date and the date of the last day of supply of the previous claim triggers a new treatment episode. If EPISODEGAPTYPE is Percentage (P), a gap of more than EPISODEGAP percent of the previous claim days of supply days between the claim date and the date of the last day of supply of the previous claim triggers a new treatment episode.

Episode Gap Type - Specifies the type of algorithm to use for the calculation of episode gaps. Valid values are: (1) F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode; and (2) P: Percentage episode gap. The value specified in EPISODEGAP will represent a percentage of the previous dispensing's days of supply to determine if two consecutive claims are in the same episode.

Enrollment Days - Optional parameter to ensure a minimum number of days of continuous enrollment prior to the start of the first treatment episode.

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

Exposure Extension Period - Extends the length of the treatment episode by a specified number of days. A treatment episode can be extended EXPEXTPER days after the last day of supply of the treatment episode's last claim.

Maximum Days Supplied - Maximum days of supply for a claim to be valid.

Minimum Days Supplied - Minimum days of supply for a dispensing to be valid.

Minimum Episode Duration - Used to reject members with first treatment episode of fewer than a certain number of days.

New Molecular Entity (NME) Indicator - Specifies whether exposures should be treated as a NME; that is, the MP algorithm will not look prior to the query period start date (either approval or launch date) when applying the washout (WASHPER) condition. This parameter has no impact on how ENRDAYS is processed, i.e., when ENRDAYS is specified the program will always look for enrollment prior to the query period start date if necessary.

Stockpiling Type - Specifies the type of stockpiling algorithm to use. Valid values are: (1) S: Standard algorithm. Slides overlapping dispensings to create a continuous sequence of non-overlapping dispensings; and (2) R: Revised algorithm. If a second dispensing occurs at least XX% (i.e., XX% or more) of the time through the previous dispensing, the length of the second dispensing is added to the end of the first dispensing; if the second dispensing occurs less than XX% of the time through the first dispensing then the second dispensing time is begun at the time it is dispensed and the first one is truncated.

Stockpiling Percent - Used in conjunction with Stockpiling Type to specify the percentage to be applied when Stockpiling Type = R

Study End Date - Query period end date.



Total Days of Supply Thresholds - Total days of supply threshold(s) for reporting. This parameter will specify how members' total days of supply (for all observed dispensings) will be stratified in the result tables examining distribution of members by number of total days supplied. For example, to have results stratified by 60 total days of supply, TOTALDAYSSUPTHRESH=060 120 180 240 300 would be entered.

Washout Period - Length of washout period in days. The washout period is a period of time before an incident exposure index date during which a member cannot have any evidence of exposure(s) of interest.

*all terms may not be used in this report

Table 1: Number of Episodes by Length, between July 1, 2009 and June 30, 2016, among Patients in the Sentinel Distributed Database (SDD)

Number of Episodes	
Patient age: 19-<61 years old	
Total number of episodes	17,595
Episodes less than or equal to 2 years	17,281
Episodes longer than 2 years	314
Patient age: 65+ years old	
Total number of episodes	17,349
Episodes less than or equal to 2 years	16,938
Episodes longer than 2 years	411

Table 2: Cumulative Days' Supply* of Teriparatide Therapy (in Years) among Patients in the Sentinel Distributed Database (SDD) between July 1, 2009 and June 30, 2016

	Number	Percent
Total		
Patients	27,784	100
Patient age: 19-<61 years old		
Patients	9,611	35
with less than 1 year of days supply	6,379	66
with less than 1-2 years of days supply	2,805	29
with more than 2 years of days supply	427	4
Patient age: 65+ years old		
Patients	18,173	65
with less than 1 year of days supply	12,314	68
with less than 1-2 years of days supply	4,804	26
with more than 2 years of days supply	1,054	6

* Cumulative days' supply is by patient and does not necessarily represent *lifetime* days' supply. Patients may have had teriparatide dispensings before or after what was captured in the Sentinel Distributed Dataset (SDD) during the study period.

Table 3: Cumulative Days' Supply* of Teriparatide Therapy (in Days) among Patients in the Sentinel Distributed Database (SDD) between July 1, 2009 and June 30, 2016

	Number	Percent
Patient age: 19-<61 years old (n=9,611)		
Patients	9,611	100.00%
with at least 1 day supply	9,611	100.00%
with at least 30 days supply	8,685	90.36%
with at least 60 days supply	7,661	79.71%
with at least 90 days supply	6,780	70.54%
with at least 180 days supply	5,224	54.35%
with at least 270 days supply	4,143	43.11%
with at least 360 days supply	3,232	33.63%
with at least 720 days supply	427	4.44%
Patient age: 65+ years old (n=18,173)		
Patients	18,713	100.00%
with at least 1 day supply	18,713	100.00%
with at least 30 days supply	16,647	88.96%
with at least 60 days supply	13,875	74.15%
with at least 90 days supply	11,975	63.99%
with at least 180 days supply	9,166	48.98%
with at least 270 days supply	7,432	39.72%
with at least 360 days supply	6,033	32.24%
with at least 720 days supply	1,086	5.80%

* Cumulative days' supply is by patient and does not necessarily represent lifetime days' supply. Patients may have had teriparatide dispensings before or after what was captured in the Sentinel Distributed Database (SDD) during the study period.



**Appendix A: Latest Date of Available Data for Each Data Partner (DP) as of Request Distribution Date
(November 14, 2016)**

DP ID	End Date
DP0001	9/30/2015
DP0002	4/30/2016
DP0003	6/30/2016
DP0004	6/30/2015
DP0005	10/31/2015
DP0006	5/31/2015
DP0007	6/30/2012
DP0008	1/31/2016
DP0009	3/31/2016
DP0010	3/31/2016
DP0011	1/31/2016
DP0012	3/31/2016
DP0013	3/31/2016
DP0014	9/30/2015
DP0015	12/31/2014
DP0016	9/30/2015

Appendix B. Specifications Defining Parameters used for Request cder_mpl1r_wp047_nsdv_v01														
Modular Program #8 was used to characterize the uptake and utilization of teriparatide.														
Enrollment Gap		45 Days												
Age Stratifications		See below												
Days of Supply Groups		0-30, 31-60, 61-90, 91+ Years												
Total Days of Supply Thresholds		001 030 060 090 180 270 360 720												
Exposure	Age Group	NME Indicator	Study Start Date	Study End Date	Wash-out Period	Enrollment Days	Minimum Days Supplied	Maximum Days Supplied	Episode Gap	Exposure Extension Period	Minimum Episode Duration	Stockpiling Type	Stockpiling Percent	
1	Teriparatide	19-<61	N	July 1, 2009	June 30, 2016	90	90	1	180	15	0	1	S*	NA
2	Teriparatide	65+	N	July 1, 2009	June 30, 2016	90	90	1	180	15	0	1	S*	NA
NDC checked against First Data Bank's "National Drug Data File (NDDF®) Plus"														