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Data obtained through 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 Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through

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

**Date Run:** March 6, 2018

**Request Description:** The purpose of this report was to compare the frequency of diagnoses for two definitions of myositis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. ICD-10-CM code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.<sup>1</sup>

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis tool, version 5.2.1

**Data Source:** This request was run against the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 123 million members. Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016 2) April 1, 2015 to September 30, 2015 and 3) April 1, 2016 to September 30, 2016. See Appendix A for a the dates of available data used in this report.

**Study Design:** We examined the incidence and prevalence of myositis across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the United States. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendices B and C for specific codes used to define each definition of myositis in this request.

**Cohort Eligibility Criteria:** Members included in the cohorts were required to be enrolled in health plans with medical and drug coverage. Individuals of all ages were included in this report.

**Incident Cohorts:** Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to myositis during which gaps in coverage of up to 45 days were allowed. Incident myositis was defined as no previous myositis in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

**Prevalent Cohorts:** There was no enrollment time requirement for members in the prevalent cohort. All qualifying diagnosis codes that occurred between October 1, 2010 and September 30, 2016 were included.

**Please refer to Appendix D for detailed specifications of parameters used in the analyses for this request.**

**Limitations:** Algorithms used to define outcomes are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind. The MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented.<sup>2</sup>

**Notes:** Please contact the Sentinel Operations Center ([info@sentinelssystem.org](mailto:info@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

<sup>1</sup>Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

<sup>2</sup>IBM Watson Health (2018). [online] [ibm.com](https://www.ibm.com/downloads/cas/OWZWJ0QO). Available at: <https://www.ibm.com/downloads/cas/OWZWJ0QO> [Accessed 01 Mar. 2019].

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## Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool\*

**Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

**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.

**Ambulatory Visit (AV)** - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

**Emergency Department (ED)** - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

**Inpatient Hospital Stay (IP)** - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

**Non-Acute Institutional Stay (IS)** - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

**Other Ambulatory Visit (OA)** - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

**Cohort Definition (drug/exposure)** - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

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

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

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

**Episodes** - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

**Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

**Event Deduplication** - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

**Exposure Episode Length** - number of days after exposure initiation that is considered "exposed time."

**Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

**Lookback Period** - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

**Maximum Episode Duration** - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Member-Years** - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

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

**Minimum Episode Duration** - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Monitoring Period** - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

**Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

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

**Treatment Episode Truncation Indicator** - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

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

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

**Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

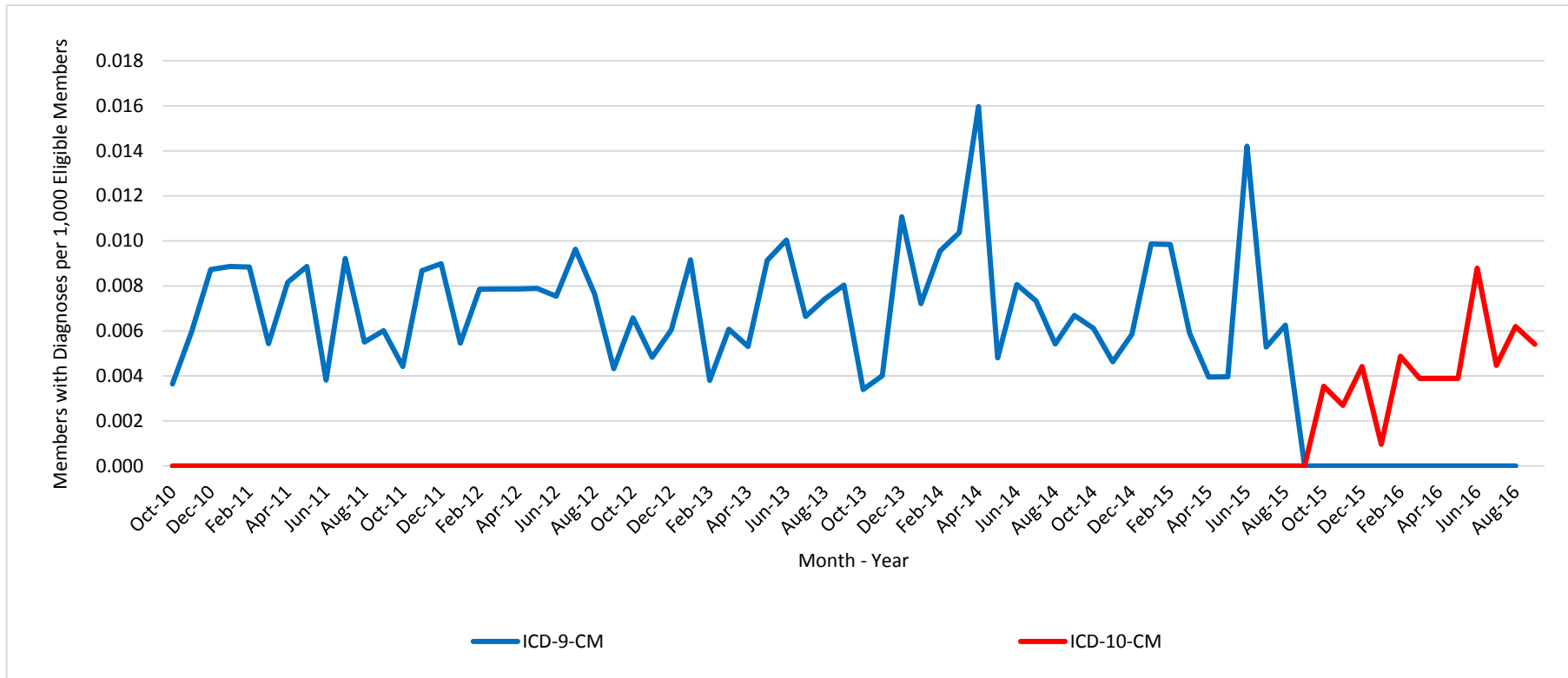
\*all terms may not be used in this report

**Table 1. Comparison of Incident\* Myositis Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)**

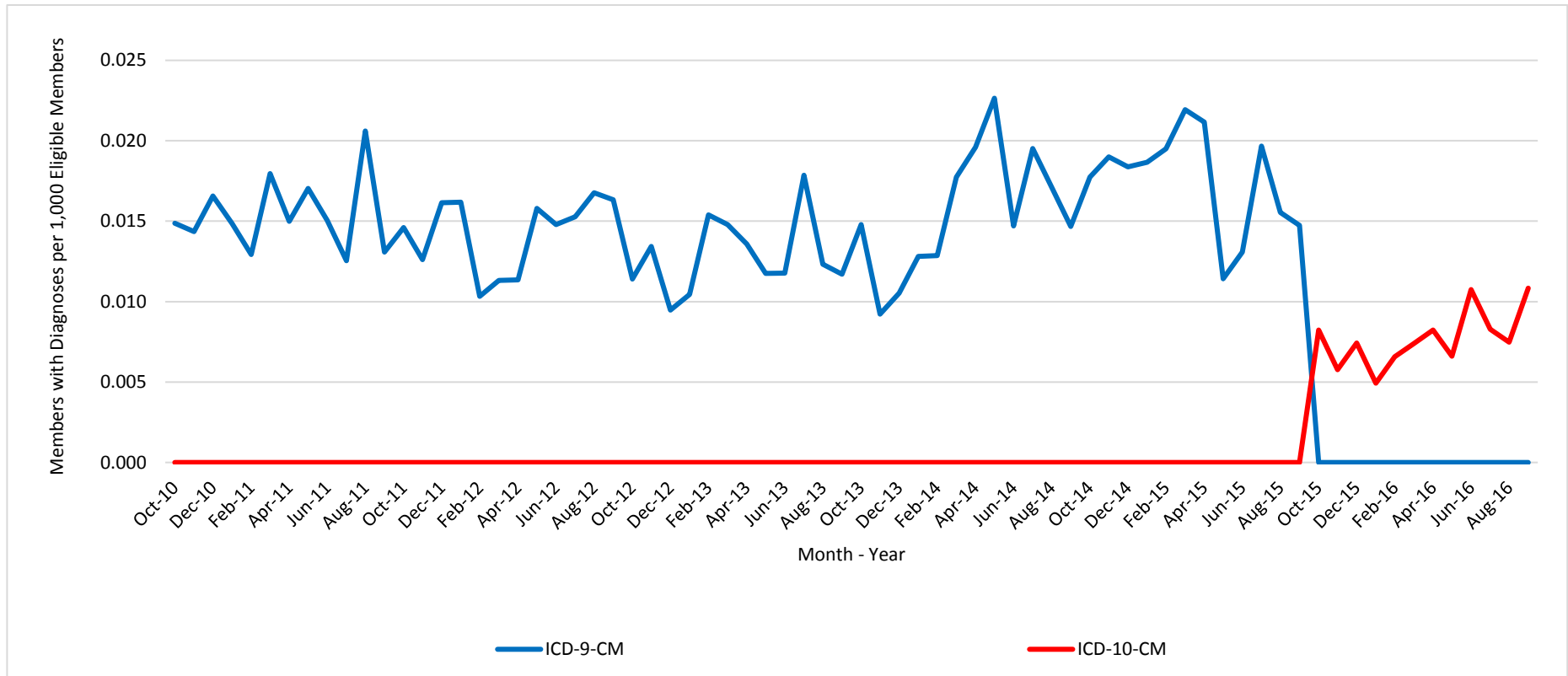
	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
<b>Myositis Definition 1</b>			
<b>ICD-9-CM: April 1, 2015 - September 30, 2015</b>			
	43	1,198,095	0.04
<b>ICD-10-CM: April 1, 2016 - September 30, 2016</b>			
	35	1,185,819	0.03
<b>Myositis Definition 2</b>			
<b>ICD-9-CM: April 1, 2015 - September 30, 2015</b>			
	15,314	1,186,827	12.90
<b>ICD-10-CM: April 1, 2016 - September 30, 2016</b>			
	15,082	1,175,479	12.83

\*Incidence defined by 183 day washout

**Figure 1. Incidence of Myositis Diagnoses (Definition 1) per 1,000 Eligible Members from October 2010 - September 2016, by Code Type, 183-Day Washout**



**Figure 2. Prevalence of Myositis Diagnoses (Definition 1) per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout**





**Figure 3. Incidence of Myositis Diagnoses (Definition 2) per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout**

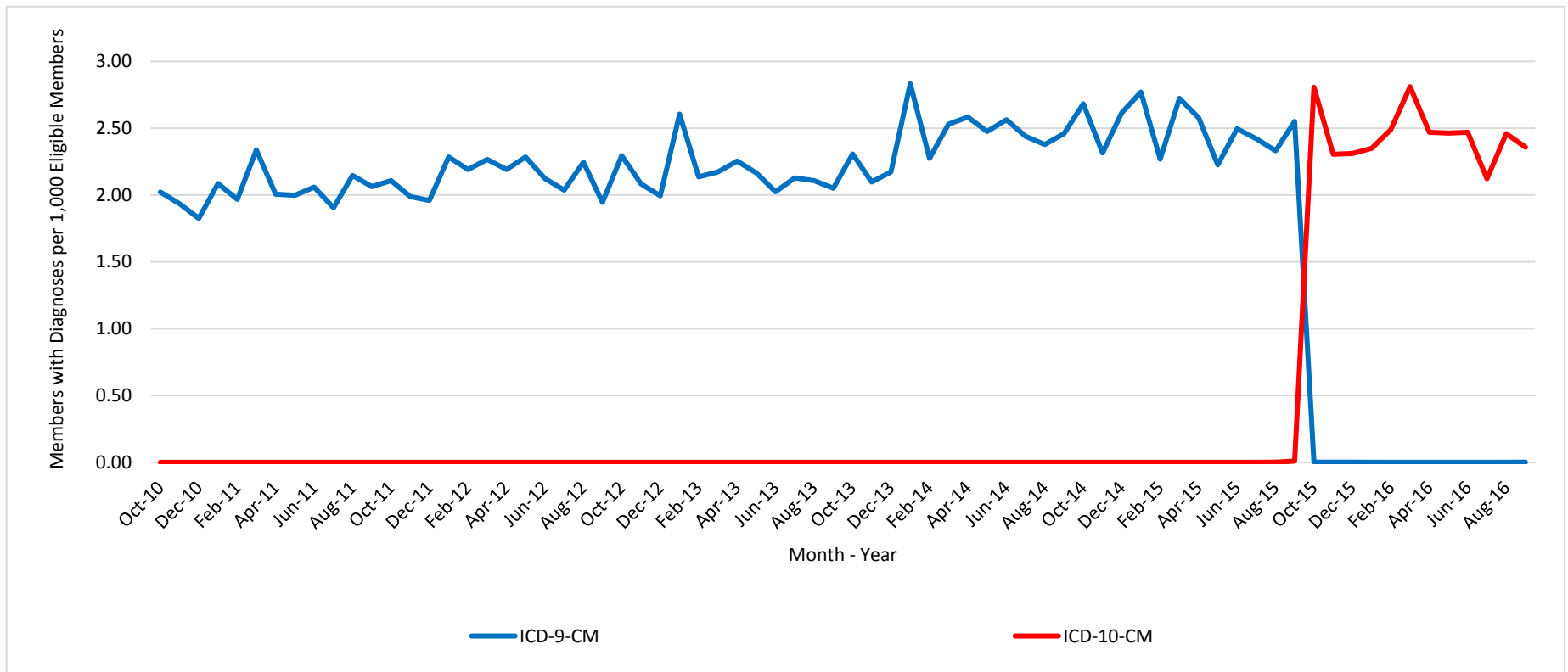
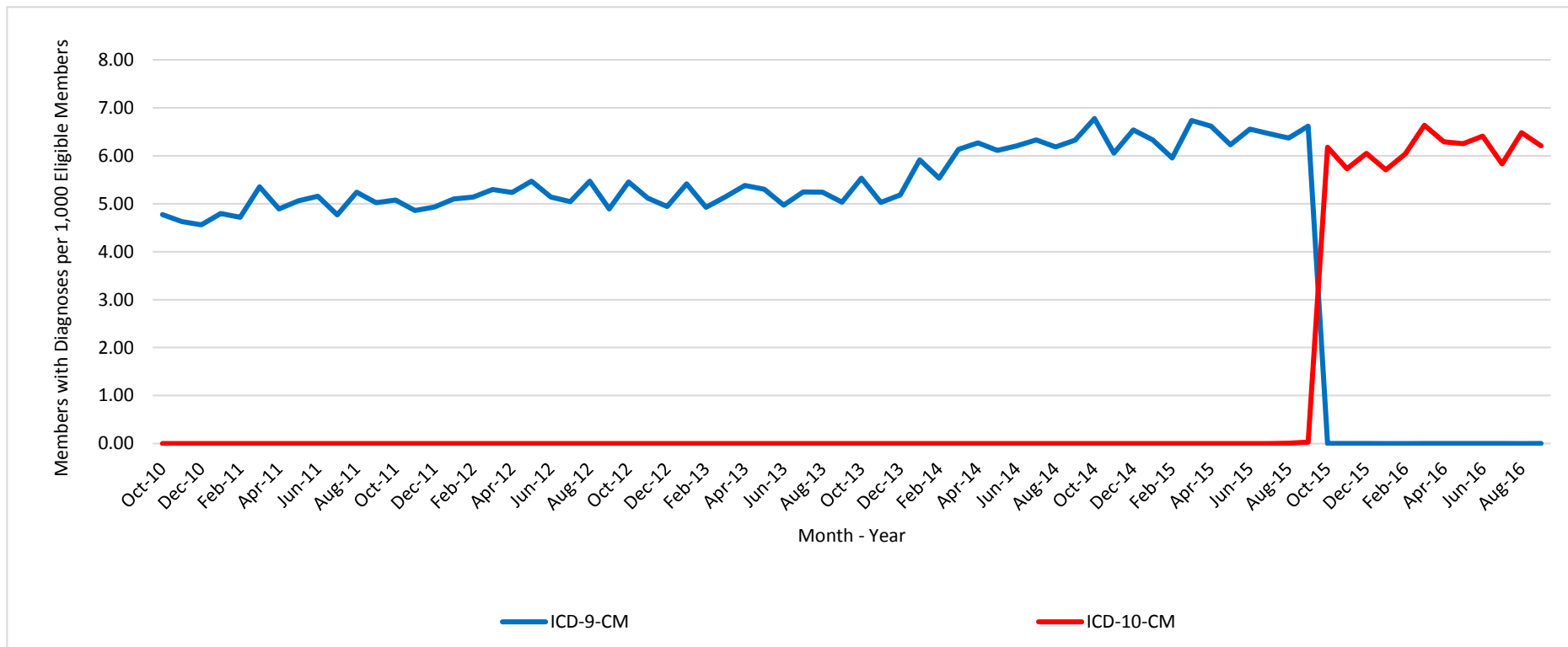


Figure 4. Prevalence of Myositis Diagnoses (Definition 2) per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout



**Appendix A. Dates Available for IBM® MarketScan® Commercial and Medicare Supplemental Databases**

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<b>Databases</b>	<b>Start Date</b>	<b>End Date</b>
IBM MarketScan Commercial and Medicare Supplemental Databases <sup>1</sup>	1/1/2010	9/30/2016

<sup>1</sup> The IBM MarketScan Databases includes a sample of 121 million employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. The IBM MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented. For more information on the IBM MarketScan Databases, please review the White Paper here: <https://www.ibm.com/downloads/cas/OWZWJ0QO>

**Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Myositis (Definition 1)**

Code	Description	Code Type
<b>ICD-9-CM</b>		
376.12	Orbital myositis	ICD-9-CM
<b>ICD-10-CM</b>		
H05.12	Orbital myositis	ICD-10-CM
H05.121	Orbital myositis, right orbit	ICD-10-CM
H05.122	Orbital myositis, left orbit	ICD-10-CM
H05.123	Orbital myositis, bilateral	ICD-10-CM
H05.129	Orbital myositis, unspecified orbit	ICD-10-CM
M60	Myositis	ICD-10-CM
M60.1	Interstitial myositis	ICD-10-CM
M60.10	Interstitial myositis of unspecified site	ICD-10-CM
M60.11	Interstitial myositis, shoulder	ICD-10-CM
M60.111	Interstitial myositis, right shoulder	ICD-10-CM
M60.112	Interstitial myositis, left shoulder	ICD-10-CM
M60.119	Interstitial myositis, unspecified shoulder	ICD-10-CM
M60.12	Interstitial myositis, upper arm	ICD-10-CM
M60.121	Interstitial myositis, right upper arm	ICD-10-CM
M60.122	Interstitial myositis, left upper arm	ICD-10-CM
M60.129	Interstitial myositis, unspecified upper arm	ICD-10-CM
M60.13	Interstitial myositis, forearm	ICD-10-CM
M60.131	Interstitial myositis, right forearm	ICD-10-CM
M60.132	Interstitial myositis, left forearm	ICD-10-CM
M60.139	Interstitial myositis, unspecified forearm	ICD-10-CM
M60.14	Interstitial myositis, hand	ICD-10-CM
M60.141	Interstitial myositis, right hand	ICD-10-CM
M60.142	Interstitial myositis, left hand	ICD-10-CM
M60.149	Interstitial myositis, unspecified hand	ICD-10-CM
M60.15	Interstitial myositis, thigh	ICD-10-CM
M60.151	Interstitial myositis, right thigh	ICD-10-CM
M60.152	Interstitial myositis, left thigh	ICD-10-CM
M60.159	Interstitial myositis, unspecified thigh	ICD-10-CM
M60.16	Interstitial myositis, lower leg	ICD-10-CM
M60.161	Interstitial myositis, right lower leg	ICD-10-CM
M60.162	Interstitial myositis, left lower leg	ICD-10-CM
M60.169	Interstitial myositis, unspecified lower leg	ICD-10-CM
M60.17	Interstitial myositis, ankle and foot	ICD-10-CM
M60.171	Interstitial myositis, right ankle and foot	ICD-10-CM
M60.172	Interstitial myositis, left ankle and foot	ICD-10-CM
M60.179	Interstitial myositis, unspecified ankle and foot	ICD-10-CM
M60.18	Interstitial myositis, other site	ICD-10-CM
M60.19	Interstitial myositis, multiple sites	ICD-10-CM
M60.8	Other myositis	ICD-10-CM
M60.80	Other myositis, unspecified site	ICD-10-CM

**Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Myositis (Definition 1)**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
M60.81	Other myositis shoulder	ICD-10-CM
M60.811	Other myositis, right shoulder	ICD-10-CM
M60.812	Other myositis, left shoulder	ICD-10-CM
M60.819	Other myositis, unspecified shoulder	ICD-10-CM
M60.82	Other myositis, upper arm	ICD-10-CM
M60.821	Other myositis, right upper arm	ICD-10-CM
M60.822	Other myositis, left upper arm	ICD-10-CM
M60.829	Other myositis, unspecified upper arm	ICD-10-CM
M60.83	Other myositis, forearm	ICD-10-CM
M60.831	Other myositis, right forearm	ICD-10-CM
M60.832	Other myositis, left forearm	ICD-10-CM
M60.839	Other myositis, unspecified forearm	ICD-10-CM
M60.84	Other myositis, hand	ICD-10-CM
M60.841	Other myositis, right hand	ICD-10-CM
M60.842	Other myositis, left hand	ICD-10-CM
M60.849	Other myositis, unspecified hand	ICD-10-CM
M60.85	Other myositis, thigh	ICD-10-CM
M60.851	Other myositis, right thigh	ICD-10-CM
M60.852	Other myositis, left thigh	ICD-10-CM
M60.859	Other myositis, unspecified thigh	ICD-10-CM
M60.86	Other myositis, lower leg	ICD-10-CM
M60.861	Other myositis, right lower leg	ICD-10-CM
M60.862	Other myositis, left lower leg	ICD-10-CM
M60.869	Other myositis, unspecified lower leg	ICD-10-CM
M60.87	Other myositis, ankle and foot	ICD-10-CM
M60.871	Other myositis, right ankle and foot	ICD-10-CM
M60.872	Other myositis, left ankle and foot	ICD-10-CM
M60.879	Other myositis, unspecified ankle and foot	ICD-10-CM
M60.88	Other myositis, other site	ICD-10-CM
M60.89	Other myositis, multiple sites	ICD-10-CM
M60.9	Myositis, unspecified	ICD-10-CM

**Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Myositis (Definition 2)**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
<b>ICD-9-CM</b>		
359.71	Inclusion body myositis	ICD-9-CM
710.4	Polymyositis	ICD-9-CM
359.4	Toxic myopathy	ICD-9-CM
359.6	Symptomatic inflammatory myopathy in diseases classified elsewhere	ICD-9-CM
359.79	Other inflammatory and immune myopathies, NEC	ICD-9-CM
359.89	Other myopathies	ICD-9-CM
359.9	Myopathy unspecified	ICD-9-CM
729.1	Unspecified myalgia and myositis	ICD-9-CM
425	Cardiomyopathy	ICD-9-CM
425.4	Other primary cardiomyopathies	ICD-9-CM
425.8	Cardiomyopathy in other diseases classified elsewhere	ICD-9-CM
425.9	Secondary cardiomyopathy unspecified	ICD-9-CM
<b>ICD-10-CM</b>		
G72.41	Inclusion body myositis [IBM]	ICD-10-CM
M33	Dermatopolymyositis	ICD-10-CM
M33.0	Juvenile dermatomyositis	ICD-10-CM
M33.00	Juvenile dermatomyositis, organ involvement unspecified	ICD-10-CM
M33.01	Juvenile dermatomyositis with respiratory involvement	ICD-10-CM
M33.02	Juvenile dermatomyositis with myopathy	ICD-10-CM
M33.03	Juvenile dermatomyositis without myopathy	ICD-10-CM
M33.09	Juvenile dermatomyositis with other organ involvement	ICD-10-CM
M33.1	Other dermatomyositis	ICD-10-CM
M33.10	Other dermatomyositis, organ involvement unspecified	ICD-10-CM
M33.11	Other dermatomyositis with respiratory involvement	ICD-10-CM
M33.12	Other dermatomyositis with myopathy	ICD-10-CM
M33.13	Other dermatomyositis without myopathy	ICD-10-CM
M33.19	Other dermatomyositis with other organ involvement	ICD-10-CM
M33.2	Polymyositis	ICD-10-CM
M33.20	Polymyositis, organ involvement unspecified	ICD-10-CM
M33.21	Polymyositis with respiratory involvement	ICD-10-CM
M33.22	Polymyositis with myopathy	ICD-10-CM
M33.29	Polymyositis with other organ involvement	ICD-10-CM
M33.9	Dermatopolymyositis, unspecified	ICD-10-CM
M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified	ICD-10-CM
M33.91	Dermatopolymyositis, unspecified with respiratory involvement	ICD-10-CM
M33.92	Dermatopolymyositis, unspecified with myopathy	ICD-10-CM
M33.93	Dermatopolymyositis, unspecified without myopathy	ICD-10-CM
M33.99	Dermatopolymyositis, unspecified with other organ involvement	ICD-10-CM
G72	Other and unspecified myopathies	ICD-10-CM
G72.0	Drug-induced myopathy	ICD-10-CM
G72.2	Myopathy due to other toxic agents	ICD-10-CM
G72.4	Inflammatory and immune myopathies, not elsewhere classified	ICD-10-CM

**Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Myositis (Definition 2)**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
G72.49	Other inflammatory and immune myopathies, not elsewhere classified	ICD-10-CM
G72.8	Other specified myopathies	ICD-10-CM
G72.89	Other specified myopathies	ICD-10-CM
G72.9	Myopathy, unspecified	ICD-10-CM
G73.7	Myopathy in diseases classified elsewhere	ICD-10-CM
M36.0	Dermato(poly)myositis in neoplastic disease	ICD-10-CM
I42.7	Cardiomyopathy due to drug and external agent	ICD-10-CM
I42.9	Cardiomyopathy, unspecified	ICD-10-CM
I43	Cardiomyopathy in diseases classified elsewhere	ICD-10-CM
I42	Cardiomyopathy	ICD-10-CM
M79.1	Myalgia	ICD-10-CM
M79.7	Fibromyalgia	ICD-10-CM
I42.5	Other restrictive cardiomyopathy	ICD-10-CM
I42.8	Other cardiomyopathies	ICD-10-CM

### Appendix D. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool was used to compare the frequency of diagnoses for two definitions of myositis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-10-CM) codes.

**Enrollment Gap:** 45 days  
**Enrollment Requirement:** 183 days for incidence scenarios; 0 days for prevalence scenarios  
**Coverage Requirement:** Medical and drug coverage

	Query Start Date	Query End Date	Event	Event Code Type	Incidence Code Type	Washout (days)	Cohort Definition	Care Setting
1	4/1/2015	9/30/2015	Myositis Definition 1	ICD-9-CM	ICD-9-CM	183	First valid event only	Any
2	4/1/2016	9/30/2016	Myositis Definition 1	ICD-10-CM	ICD-10-CM	183	First valid event only	Any
3	4/1/2015	9/30/2015	Myositis Definition 2	ICD-9-CM	ICD-9-CM	183	First valid event only	Any
4	4/1/2016	9/30/2016	Myositis Definition 2	ICD-10-CM	ICD-10-CM	183	First valid event only	Any
5	10/1/2010	9/30/2016	Myositis Definition 1	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
6	10/1/2010	9/30/2016	Myositis Definition 1	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
7	10/1/2010	9/30/2016	Myositis Definition 2	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
8	10/1/2010	9/30/2016	Myositis Definition 2	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	All valid events	Any
9	10/1/2010	9/30/2016	Myositis Definition 1	ICD-9-CM	N/A	0	All valid events	Any
10	10/1/2010	9/30/2016	Myositis Definition 1	ICD-10-CM	N/A	0	All valid events	Any
11	10/1/2010	9/30/2016	Myositis Definition 2	ICD-9-CM	N/A	0	All valid events	Any
12	10/1/2010	9/30/2016	Myositis Definition 2	ICD-10-CM	N/A	0	All valid events	Any

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.