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Myocarditis/Pericarditis Rates following 2023–2024 COVID-19 mRNA Vaccinations from CBER's (b) (6)

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Center for Biologics Evaluation and Research
U.S. Food & Drug Administration

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This presentation is provided in lieu of manufacturer notification letters.

Methods



Data Sources	Commercial Insurance Databases • Carelon Research: Elevance Health, including Anthem, and affiliated health plans • CVS Health: Aetna and affiliated health plans • Optum: Commercial health plans Claims supplemented with vaccination data from local and state Immunization Information System data (IIS)
Study Population	• Persons 6 months–64 years of age at vaccination • Continuous enrollment 365 days prior to vaccination
Exposure	2023–2024 COVID-19 mRNA vaccination
Outcome	• Incident myocarditis/pericarditis in any care setting 1–7 days following vaccination • Myocarditis/pericarditis cases were not chart confirmed

Statistical Analysis

- Rates per million vaccine doses with 95% exact Poisson confidence intervals
- Population
 - All persons 6 months–64 years of age
 - Males 12–25 years of age
 - Males 16–25 years of age

Myocarditis/Pericarditis Rates 1–7 Days Following 2023–2024 COVID-19 mRNA Vaccinations

Population	No. Doses	No. Cases	Rate Per Million Vaccine Doses (95% CI)
All persons 6 months–64 years of age	3,573,374	30	8.4 (5.7, 12.0)
Males 12–25 years of age	199,887	5	25.0 (8.1, 58.4)
Males 16–25 years of age	132,142	5	37.8 (12.3, 88.3)



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Supplemental Slides

Myocarditis/Pericarditis Claims Algorithms

At least one of the following diagnosis codes for myocarditis/pericarditis		
Code	Code Type	Description
B3322	ICD-10-CM	Viral myocarditis
B3323	ICD-10-CM	Viral pericarditis
I300	ICD-10-CM	Acute non-specific idiopathic pericarditis
I301	ICD-10-CM	Infective pericarditis
I308	ICD-10-CM	Other forms of acute pericarditis
I309	ICD-10-CM	Acute pericarditis, unspecified
I32	ICD-10-CM	Pericarditis in diseases classified elsewhere
I41	ICD-10-CM	Myocarditis in diseases classified elsewhere
I400	ICD-10-CM	Infective myocarditis
I401	ICD-10-CM	Isolate myocarditis
I408	ICD-10-CM	Other acute myocarditis
I409	ICD-10-CM	Acute myocarditis, unspecified
I514	ICD-10-CM	Myocarditis, unspecified