

ADVERSE EVENT TABLE-CANDIDACY REPORT

Myocarditis

Candidate injury	Myocarditis
Countermeasure(s)	mRNA-1273, BNT162b2 (dose 2 especially)
Program(s) targeted	VICP amendment and CACP table establishment (screening assessment)
Report version / generation	v1.0 / 2026-09-05
Evidence cutoff	July 2026 (site card pipeline build date)
Current table status	Not verified from a live HRSA table pull; not asserted by the source card.

1. Executive summary and recommended determination

The source card classifies **Myocarditis** as **Probable** in its WHO-UMC framework. It describes 1-5 days post-vaccination; median 2-3 days and reports: mRNA vaccines cause myocarditis in adolescents/young adults, especially after dose 2. Biopsy-confirmed lymphocytic infiltrate (macrophages, CD8+ T cells, B cells); peak onset 2-4 days post-vaccination. Causality is now considered established by national vaccine safety reviews (e.g., US National Academies evidence review). This report is a source-bounded screening dossier, not a completed rulemaking record.

Provisional classification: Tier 1 Established. **Blocker:** the supplied card does not provide the complete A/B scoring rule, controlled epidemiologic estimates, live claims data, or a complete case register required for a final table recommendation.

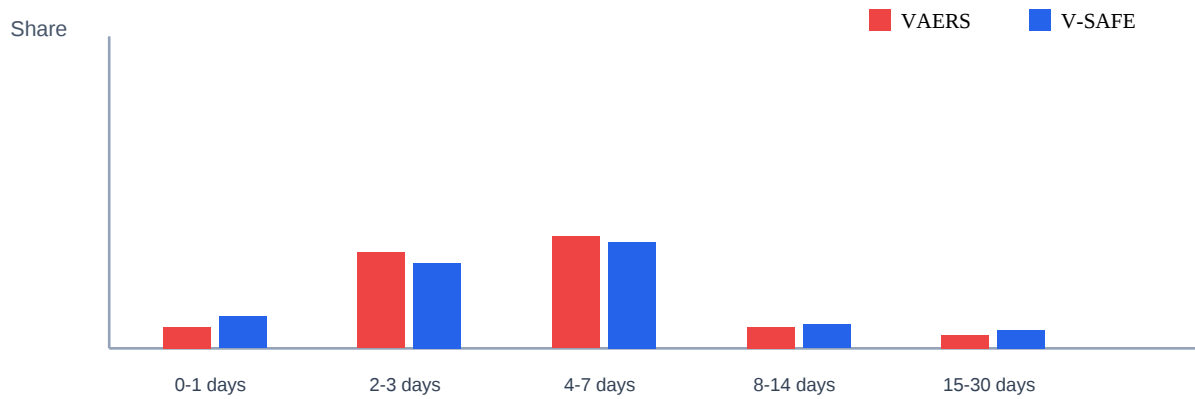
Draft proposed table language: COVID-19 vaccine(s) specified above | Myocarditis | 1-5 days post-vaccination; median 2-3 days | Draft only: clinically diagnosed condition meeting accepted case definition; individual causation and alternate causes require adjudication.

2. Current claims context

No live HRSA CACP/VICP claims query was supplied or performed for this report. Counts of allegations, decisions, eligibility findings, and denial reasons are therefore not available and must be populated from a dated HRSA extract before use in a petition or rulemaking record.

3. Temporal distribution: VAERS vs V-SAFE

V-SAFE Status: Significantly Elevated



Onset bucket	VAERS	V-SAFE
0-1 days	VAERS: 8% (8% of reports in this chart)	V-SAFE: 12% (12% of reports in this chart)
2-3 days	VAERS: 36% (36% of reports in this chart)	V-SAFE: 32% (32% of reports in this chart)
4-7 days	VAERS: 42% (42% of reports in this chart)	V-SAFE: 40% (40% of reports in this chart)
8-14 days	VAERS: 8% (8% of reports in this chart)	V-SAFE: 9% (9% of reports in this chart)
15-30 days	VAERS: 5% (5% of reports in this chart)	V-SAFE: 7% (7% of reports in this chart)

Interpretation limitation: VAERS is passive reporting and the card does not provide denominators, case definitions, validation methods, or the underlying V-SAFE query. These distributions establish neither incidence nor causation on their own.

4. Biological plausibility and mechanistic evidence (Checklist A)

The source card provides no mechanism block for this condition.

Checklist item	Status in supplied source	Evidence-bound finding
A1	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A2	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A3	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A4	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A5	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A6	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A7	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A8	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.
A9	Not assessable	The attached structure names A1-A9 but does not define the item or scoring criterion; the card alone cannot be mapped reliably.

5. Epidemiological evidence (Checklist B)

The supplied card gives a V-SAFE status and a temporal plot, but no PRR/ROR, confidence intervals, controlled RR/OR estimates, denominator, database pull date, or named cohort/case-control/SCCS analysis. It therefore cannot establish a quantitative epidemiological effect size or determine whether a CICP evidentiary threshold is met.

Checklist item	Status in supplied source	Evidence-bound finding
B1	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B2	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B3	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B4	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B5	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B6	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B7	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B8	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B9	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.
B10	Not assessable	The attached structure names B1-B10 but supplies neither their definitions nor the needed underlying study results.

6. Composite scoring and precedent comparison

Result: No numeric composite can be calculated. The structure document refers to an A/B checklist scoring rule but does not provide it, and all A/B items are not assessable from the source card. The source-only provisional label is Tier 1 Established.

Comparator	Use in this report
SIRVA	Named by the supplied structure as a potential comparator; no evidence record supplied.
Rotavirus/intussusception	Named by the supplied structure; no condition-specific comparison supplied.
Anaphylaxis	Named by the supplied structure; no formal comparator analysis supplied.

7. Case-report / case-series literature

The source card states 180 published case reports. It is explicitly described on the page as curated rather than a systematic review. Publication years and geographic spread are not comprehensively available from the card.

The count exceeds the structures default threshold of 15. A separate full case-report register is required, but cannot be generated because the source card does not expose the underlying one-row-per-case data (citation, patient count, exposure, latency, outcome).

8. Precedent and QAI drafting appendix

Non-final QAI-style draft: Myocarditis may be considered only when the clinical diagnosis meets an accepted case definition and onset occurs within 1-5 days post-vaccination; median 2-3 days. This source alone does not establish product-specific scope, exclusions, or an evidentiary basis for a presumption of causation.

Nesting versus a new category cannot be determined from the supplied source because existing Table categories and qualifications were not provided.

9. Bibliography (deduplicated card citations)

1. [OBSERVATIONALMyocarditis following COVID-19 vaccination: incidence, mechanisms, and clinical considerations](https://pmc.ncbi.nlm.nih.gov/articles/PMC9115793/) (https://pmc.ncbi.nlm.nih.gov/articles/PMC9115793/)
2. [OBSERVATIONALMyocarditis, Pericarditis, and COVID-19 Vaccines](https://www.ncbi.nlm.nih.gov/books/NBK607369/) (https://www.ncbi.nlm.nih.gov/books/NBK607369/)
3. [CLINICALClinical Characteristics of Patients with Myocarditis following COVID-19 mRNA Vaccination: A Systematic Review and Meta-Analysis](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9369856/) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9369856/)
4. [OBSERVATIONALThe Epidemiology of COVID-19 Vaccine-Induced Myocarditis](https://onlinelibrary.wiley.com/doi/10.1155/2024/4470326) (https://onlinelibrary.wiley.com/doi/10.1155/2024/4470326)
5. [OBSERVATIONALMyocarditis Following COVID-19 Vaccine: What Did We Learn?](https://pmc.ncbi.nlm.nih.gov/articles/PMC12220863/) (https://pmc.ncbi.nlm.nih.gov/articles/PMC12220863/)
6. [IN VITROExploring ceRNA mechanisms in COVID-19 mRNA vaccine-induced myocarditis: implications for future vaccine design](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC12586086/) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC12586086/)

Source and limitations

Primary source: the WHO-UMC Causality Assessment card for this condition in the local covid-vaccine.html page. The page states that its literature is curated, not a systematic review, and that matching refuting/null searches are not logged with hit counts. This report preserves those limitations and should be supplemented with verified primary studies, a reproducible claims pull, the A/B checklist definitions, and a complete case register before external use.