ADVERSE EVENT TABLE-CANDIDACY REPORT

# Myopericarditis

| | |
|---|---|
| **Candidate injury** | Myopericarditis |
| **Countermeasure(s)** | mRNA-1273, BNT162b2 |
| **Program(s) targeted** | VICP amendment and CICP 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 **Myopericarditis** as **Probable** in its WHO-UMC framework. It describes 2-4 days post-vaccination and reports: Concurrent myocarditis and pericarditis (myopericarditis) occurs in a subset of mRNA vaccine recipients with cardiac adverse events, sharing the same inflammatory mechanism and a similar 2-4 day onset window as isolated myocarditis. 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.

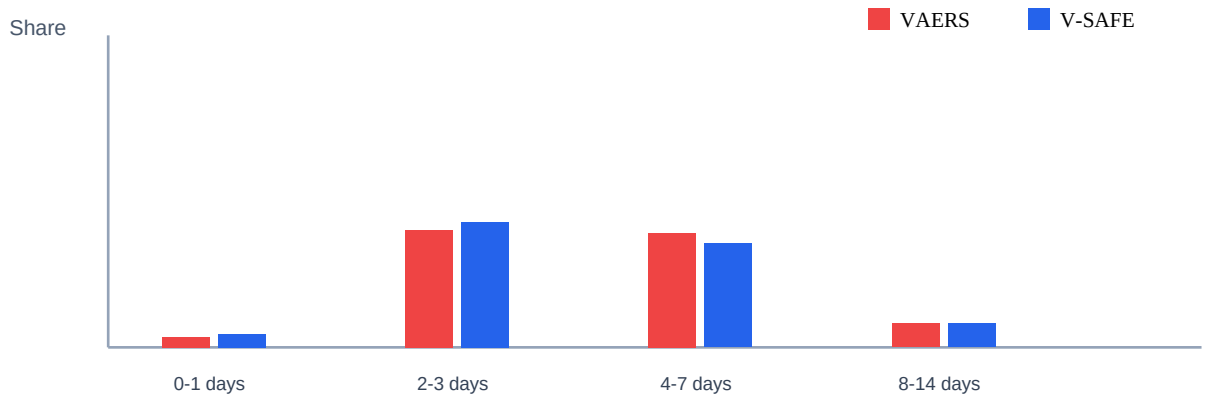
**Draft proposed table language:** COVID-19 vaccine(s) specified above | Myopericarditis | 2-4 days post-vaccination | Draft only: clinically diagnosed condition meeting accepted case definition; individual causation and alternate causes require adjudication.

## 2. Current claims context

No live HRSA CICP/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: n=5 (4% of reports in this chart) | V-SAFE: 5% (5% of reports in this chart) |
| 2-3 days | VAERS: 44% (44% of reports in this chart) | V-SAFE: 47% (47% of reports in this chart) |
| 4-7 days | VAERS: 43% (43% of reports in this chart) | V-SAFE: 39% (39% of reports in this chart) |
| 8-14 days | VAERS: 9% (9% of reports in this chart) | V-SAFE: 9% (9% 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 23 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:** Myopericarditis may be considered only when the clinical diagnosis meets an accepted case definition and onset occurs within 2-4 days post-vaccination. 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. CLINICALCOVID-19 Vaccination-Induced Myopericarditis: An Imager's Perspective (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8800170/)

2. CASE-REPORTA Case Series of Myocarditis Related to the COVID-19 Vaccine (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9631103/)


## 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.*