Michigan Department of Health and Human Services

Monoclonal Antibody Therapy - Patient Profile Worksheet (v 2.0)

This worksheet is intended to facilitate data collection regarding the administration of monoclonal antibody (mAb) therapy provided through the Michigan Department of Health and Human Services. This form may be adapted to meet the needs of healthcare facilities. Note, revisions may occur to the electronic form resulting in differences between this worksheet and the current electronic version.

Please complete this patient profile survey for each patient treated with monoclonal antibody (MAB) therapy supplied through the State of Michigan. This information is being requested by the Michigan Department of Health and Human Services (MDHHS) in accordance with the Michigan Public Health Code (MCL 331.531). This questionnaire was determined to not be designed for a research purpose through consultation with the MDHHS Institutional Review Board. In completing this questionnaire, you will be asked to include a unique internal number to associate the patient data on this form with a follow-up form intended to be used if the patient is later admitted to the hospital or known to have died. This may be accomplished by simply assigning a unique identifier to each patient receiving the medication. For example, if a hospital provides the medication to 4 patients, they may be numbered 1 to 4. This information should be retained to allow the hospital to expeditiously complete the follow-up form to avoid re-entering data previously captured. No patient identifying information should be disclosed on this form outside of the information requested. Thank you for providing this important information.

1. Hospital (or healthcare facility) who originally received MAB medication.

2. Hospital (or healthcare facility) who admistered MAB medication (if same as above, enter "same")

3. Name of person completing this form.

4. Email address of person completing this form.

5. Please assign a unique identifier for this patient (as described above) that will be used to facilitate data entry into a follow-up questionnaire, if needed. Retain this number for potential future use.

Usually provided by pharmacy

6. Patient age (in years)? Enter only numbers.

7. Patient gender?
    - Male
    - Female

8. Patient race?
    - A. American Indian or Alaska Native
    - B. Asian
    - C. Black or African American
    - D. Hispanic or Latino
    - E. Native Hawaiian or Other Pacific Islander
    - F. White
    - G. Unknown

9. Patient home zip code?

10. Patient's phone number?

11. Is the patient a healthcare worker (including EMS)?
    - Yes
    - No

12. Symptom onset date (estimate if uncertain)

13. Has the patient tested positive for COVID-19?
    - Yes
    - No (Note: Positive test required for mAb therapy)

14. Date of COVID-19 Test

15. Presenting signs and symptoms at the time of the clinical evaluation resulting in the order for MAB therapy. Check all that apply.
    - A. Patient complains of any shortness of breath
    - B. Patient with any recorded respiratory rate above 20
    - C. Patient with any recorded pulse/heart rate above 95
    - D. Any other COVID-19 symptoms (headache, cough, fever/chills, fatigue, body aches, sore throat)
    - E. No symptoms (Note: Asymptomatic patients do not qualify for MAB-therapy)

16. For adult patients (age > 17 YO) please identify any of the following risk factors for developing severe COVID-19 disease. Select all that apply.
    - A. Age >64 years old
    - B. Age >54 years old AND PMH of cardiovascular disease, or hypertension, or COPD/other chronic respiratory disease
    - C. BMI > 34
    - D. Chronic Kidney Disease
    - E. Diabetes
    - F. Immunosuppressive disease
    - G. Current immunosuppressive treatment
    - H. None of the above (Note: Patient must have at least one risk factor for MAB therapy)
    - I. Patient is not an adult (age <18 YO)

17. For pediatric patients (age >11 YO and <18 YO) please identify any of the following risk factors for developing severe COVID-19 disease. Select all that apply.
    - A. BMI ≥85th percentile for their age and gender based on CDC growth charts
    - B. Sickle cell disease
    - C. Congenital or acquired heart disease
    - D. Neurodevelopmental disorders (e.g., cerebral palsy)
    - E. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)
    - F. Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
    - G. None of the above (Note: Patient must have at least one risk factor for MAB therapy)
    - H. Patient is an adult (age >17)

18. Date of MAB therapy?

19. Which of the following best describes the setting the MAT-therapy was administered in.
    - A. Emergency department
    - B. Infusion center (general)
    - C. Infusion center (COVID-19 specific)
    - D. Outpatient clinic
    - E. Urgent care
    - F. Long term care facility (including skilled nursing facility)
    - G. Homecare setting
    - H. Other: (describe)_____

20. MAB therapy administered?
    - Bamlanivimab
    - Casirivimab and imdevimab
    - Other: (specify)_____

21. Identify any of the following infusion-related signs or symptoms that occurred during or within 60 minutes of completion of administration? Select all that apply.
    - A. Fever or chills
    - B. Nausea
    - C. Headache
    - D. Bronchospasm
    - E. Hypotension (SBP <90 mmHg)
    - F. Angioedema
    - G. Throat irritation
    - H. Rash, including urticaria
    - I. Pruritus
    - J. Myalgia
    - K. Dizziness
    - L. No infusion-related signs or symptoms were reported
    - M. Other: (describe)_____

22. Describe the circumstance and outcome associated with any infusion-related signs or symptoms. If none enter "N/A"

23. After the administration of the mAb therapy, where did the patient go?
    - A. Home
    - B. Skilled nursing facility
    - C. Other long-term care facility (e.g., assisted living, etc)
    - D. Patient admitted to hospital (planned hospital admission is a contraindication to mAb therapy).
    - E. Other: (specify)_____

24. Please provide any additional information you believe to be relevant to this use of MAT-Therapy.