Monoclonal Ab Infusion Readiness Checklist (IHS v11.11.20)

**Activity 1: Define facilities and patient visit logistics**

**Activity 2: Ensure sufficient supplies**

**Activity 3: Develop plan for staffing and personnel**

**Activity 4: Review drug administration process**

**Activity 5: Prepare for reimbursement and drug ordering**

**Activity 6:** **Reporting process**

Accreditation

* Meet accreditation standards for infusion services including (but not limited to) governance/scope of practice, provider/nurse staffing, credentialing, patient safety, emergency protocols, pharmacy, infection control, lab.

Facilities

* Dedicated physical space for infusion services (& capacity).

Lab Testing

* Capacity for direct SARS-CoV-2 viral testing/results.

Supplies

* Infusion equipment (pump/gravity) on site.
* Monitoring equipment.
* Emergency equipment.

Staffing

* Communication plan for facility staff.
* On site medical, pharmacy, lab, and nursing staff with capacity for a dedicated outpatient infusion team.
* Administration by qualified healthcare professional.
* Clinical capacity to prepare, deliver, and monitor infusion over 1 hour with observation 1-hour post infusion for patients 12 years and older (pediatric/adult).

Infection Control

* Capacity for physical distancing/patient cohorting.
* Adequate PPE and fit-testing (as indicated).
* Exposure control policies and procedures.
* Negative airflow.
* Terminal cleaning.

Safety

* EUA informed consent protocol.
* Capacity to confirm patient eligibility according to EUA criteria.
* Capability to respond to anaphylaxis and/or infusion reactions (tested by conducting a mock code of this scenario to assure preparedness).

Pharmacy

* Procurement process.
* Cold chain (2-8 degrees Celsius) storage capacity.
* Equipment (biosafety hood).
* Infusion preparation using aseptic technique.

Reporting

* Process for FDA MedWatch mandatory reporting of all medication errors and serious adverse events.

Other

* Prioritization
* Standing orders
* Billing/Reimbursement