Handling Difficult Questions from Patients or Caregivers Regarding COVID-19 Monoclonal Antibody Products

1. **Why can't anyone get the medication?**
    a. These products do not yet have formal approval from the Food and Drug Administration (FDA). With the small amount of evidence available, the FDA granted an Emergency Use Authorization for these monoclonal antibody products. In this authorization, patients who are at high-risk and most likely to benefit from one of these medications may be considered for treatment. Unfortunately, those not belonging to one of the high-risk groups will not be considered under the FDA guidance at this time.
2. **What is the Random Allocation Process?**
    a. The random allocation process is a way to fairly and equally provide this medication to patients at high-risk. Given that there are many people with COVID-19 who would qualify, but only a small amount of medication, the random allocation process ensure every person has an equal chance of receiving this medication. Selection does not guarantee medication administration, as supply and infusion locations may be limited. Additionally, selection by the random allocation system is for an individual patient, and are non-transferrable to others.
3. **It sounds like you are rationing.**
    a. What we are doing is trying to spread out our resources in the best way possible to ensure all eligible patients have an equal chance at receiving one of these medications. This is a time where we wish we had more for every single person who qualifies under the FDA criteria.
4. **Can't you get more medication?**
    a. Presently, the company only has a limited supply of the medication which is not enough to meet the demand. The supply is being allocated to states based on population and COVID-19 case numbers. From there, states are allocating to hospitals and infusion centers. We are not in control of how much medication we receive or when we will receive additional supply.
5. **What happens if I cannot make an infusion appointment before the end of day 10 from symptom onset?**
    a. Based on the FDA criteria issued under the Emergency Use Authorization, infusions should be completed by day 10 from symptom onset. Beyond this date, it is unknown whether the medication will provide any benefit as your immune system has likely begun making its own antibodies against the virus. Every effort will be made to schedule an infusion appointment before the end of day 10; however, if you do not make your appointment or cannot schedule in that time frame you are no longer eligible to receive this medication and it will be allocated to another eligible patient selected by the random allocation process. You may not designate an alternative person to receive medication (i.e. selection is non-transferrable).

“SHARE” Talking about resource allocation

Show the guideline and set expectations about the availability and process for obtaining the allocated product: “Here’s what our institution / system / region is doing for patients with this condition.”

Headline what it means for the patient’s care: “So for you, what this means is that not everyone who is a candidate for the medication will receive it. After discussing the risks and benefits of the monoclonal antibody medication, if the decision is made to order the medication then I (a prescriber) will enter your information in to the random allocation system. If you are randomly selected to receive the medication, an order for the medication at one the participating infusion locations will be sent. From there, you will work with a scheduling representative to identify a date/time within the 10 day window from symptom onset to receive the medication.”

Affirm the care you will provide: “We will be doing [the care plan], and we hope you will recover soon.”

Respond to emotion: “I can see that you are concerned.”

Emphasize that the same rules apply to everyone: “We are using the same rules with every other patient in this hospital / system /institution, so that no one is singled out.”