Providing access to anti-severe acute respiratory syndrome coronavirus 2–neutralizing monoclonal antibody (MAb) infusions to ambulatory patients with early-onset Covid-19 poses numerous operational challenges to health care systems. Among these include optimizing efficacy through early identification of high-risk patients, ensuring equitable access to disadvantaged populations and across wide geographic regions, preserving access to infusion services for other populations, maintaining adequate infection control, and managing resource constraints. Intermountain Healthcare shares its experience designing and implementing a novel care delivery pathway for MAb therapy to address these challenges within a large integrated health care system. By describing adaptable and scalable solutions, the authors hope to illustrate the real-world feasibility of implementing these promising therapies in health care systems, large and small, to improve patient outcomes and preserve hospital capacity.

**KEY TAKEAWAYS**

» By interfacing with the state health department to address scarcity in infusion capacity, available monoclonal antibody treatments were matched to patients who would benefit the most.

» A novel care delivery model leveraging telehealth, redeployed caregivers, and geographically decentralized infusion sites optimized access, equity, and shared decision-making for patients with Covid-19.
We created a patient-centered yet public health–oriented initiative as part of our organization’s ongoing collaboration with the state public health department and incident command’s response to the pandemic.

The Challenge

Intermountain Healthcare is a nonprofit health care system that provides medical services across the state of Utah and in some communities of southern Idaho and Nevada. Through its 23 hospitals and 215 clinics, Intermountain employs approximately 2,400 physicians and advanced practice providers (APPs), with an additional 3,800 affiliated physicians within its coverage area. Intermountain also has its own health insurance plan, which covers approximately 900,000 patients, although it also contracts with other payers. Additionally, Intermountain provides more than $200 million in charity care annually to low-income and uninsured patients.

During the rapid onset of the Covid-19 pandemic, health care operations were required to incorporate scientific discovery and innovation at a scale previously unseen. By November 21, 2020, emergency use authorization (EUA) approval was granted by the FDA for two monoclonal antibody (MAb) products, bamlanivimab (later paired with etesevimab; Eli Lilly and Company, Indianapolis, IN) and casirivimab-imdevimab (Regeneron, Tarrytown, NY), for use in nonhospitalized patients with early mild to moderate Covid-19. Early trial data suggested that these MAb could decrease the likelihood of hospitalization in high-risk patients; however, despite their potential benefits to both patients and hospitals, MAb treatments in the outpatient setting showed lackluster early uptake because of logistical barriers.

Against that background, our team was challenged to rapidly set up an MAb infusion program that could serve as a “release valve” on our overburdened hospitals as Covid-19 cases ballooned through the winter of 2020. As a regional health care system, we also needed to coordinate these activities over a large geographic area in an efficient and equitable way that preserved access to existing infusion resources and would be sustainable over a time frame of weeks to months.

The Goal

Our goal was to create a program that would equitably and efficiently provide access to MAb infusions across the state of Utah using existing resources within our integrated health care system. Our time frame was to go live within 2 weeks of the EUA being issued for Covid-19 MAb therapy.

“Our team was challenged to rapidly set up an MAb infusion program that could serve as a “release valve” on our overburdened hospitals as Covid-19 cases ballooned through the winter of 2020.”
The Execution

Our program implementation strategy comprised three primary components:

- A decentralized network of strategically located infusion sites capable of providing safe administration of MAb infusions to patients with Covid-19 across a large geographic region;
- A team of redeployed telehealth clinicians who proactively identified eligible high-risk patients at the point of positive test notification; and
- An efficient system of matching eligible patients with the closest available infusion location, coordinating infusion delivery across sites and standardizing management of possible infusion reactions.

The Team

To set up and maintain a care delivery infrastructure accessible to patients with Covid-19 across the state of Utah, the MAb delivery program was designed by a core group of leaders representing key components of the program. Rapid program design and implementation was supported by executive leadership under the pandemic incident command structure. During planning and implementation, short daily meetings or “huddles” were used to troubleshoot problems in real time, such as staffing issues or medication supply shortages (Table 1). Thanks to an innovative HR pandemic redeployment program, we were able to quickly assemble a team of physicians and APPs, whom we refer to as the “MAb Squad.”

Hurdles

Matching Initial Scarcity to Demand at the State Level

Under the EUA criteria, approximately 27% of patients with Covid-19 would be potentially eligible for MAb therapy; however, the supply of medication allotted to our state by the U.S. Department of Health and Human Services (HHS) was only sufficient to treat 2 to 3%. How to manage this scarcity was addressed by the Utah Incident Command and Crisis Standards of Care Scarce Medication Subcommittee. This committee had representation from all major health care delivery systems in the state, including our own.

During initial meetings, the committee determined that the goals of MAb distribution should be to maximize efficacy and equity by matching available infusion capacity to patients at highest probability of hospitalization. To do this, the committee evaluated available risk stratification models and decided upon a simple scoring tool validated in a large, representative local population and based on accurate discrimination for both hospitalization and mortality. An eligibility threshold was then chosen that would match the available capacity to the number of new cases identified at that threshold, creating an adaptive method of continuous supply-demand matching. The committee then coordinated site selection to strategically ensure that locations were distributed equitably across the state.
Once the statewide treatment criteria were established, we could focus on finding eligible patients within our own health care system. To do this, we adapted an existing electronic clinical trial screening platform, developed by Intermountain’s in-house data analytics team, to identify patients with early symptomatic Covid-19 and flag them for MAb therapy. This platform uses a daily list of patients with positive Covid-19 tests from the previous day. Analysts developed a method for querying the enterprise data warehouse for available chronic conditions and other variables to calculate the state risk score for each patient on the daily test notification list, insofar as these clinical data were available. This generated an “e-screened” list of patients whom a provider on the MAb Squad could call to complete the screening process.

**Identifying and Enrolling Eligible Patients**

Table 1. Roles and Responsibilities of the Intermountain Covid-19 Monoclonal Antibody Program Team

| Role                                      | Responsibilities                                                                                                                                                                                                 | Count |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Program Directors                         | Develop vision for program; coordinate with health system executives and incident command structure; report on progress/outcomes; address operational issues; perform outreach/education; ensure geographic strategy                      | 3     |
| * Medical Director, ID (Chair, Covid-19 Therapeutic Committee) |                                                                                                                                                                                                                           |       |
| * Medical Director, Telehealth             |                                                                                                                                                                                                                           |       |
| * Infectious Disease Pharmacist           |                                                                                                                                                                                                                           |       |
| UC Service Line Medical Director          | Operational decisions at UC clinics; assist in site selection; coordinate infusion site personnel; MAb program champion                                                                                            | 1     |
| UC Service Line Operations Director       | Operational decisions at UC clinics; assist in site selection; develop business case; coordinate billing/financial aid/reimbursement; manage supply chain                                                                 | 1     |
| UC Clinic Manager                         | Management of day-to-day operational issues; MAb program champion; staff training; workflow development including patient registration, appointment availability; manage supply chain; development of infusion protocol | 1     |
| Infusion Center Operations Director       | Operational decisions at infusion centers; assist in site selection; develop business case; coordinate billing/financial aid/reimbursement; manage supply chain                                                                            | 2     |
| Infusion Center Managers                  | Management of day-to-day operational issues; MAb program champion; staff training; workflow development including patient registration, appointment availability; manage supply chain; development of infusion protocol | 3     |
| Pharmacy Team                             | Manage distribution of drug to MAb sites; monitoring and reporting of adverse events; drug reconstitution; IV pump programming; liaise with clinical informatics on electronic order                          | 2     |
| * Supply Chain Pharmacist                 |                                                                                                                                                                                                                           |       |
| * Infusion Pharmacist                     |                                                                                                                                                                                                                           |       |
| Redeployed Providers                      | Determine patient eligibility; provide MAb education, place orders for treatment                                                                                                                                       | 9     |
| Redeployed RN                             | Assist providers with contacting, consenting, and educating patients                                                                                                                                                | 1     |
| Informatics/Analytics                     | Build and maintain electronic orders; report data to federal government and internally; build website and provide IT support                                                                                         | 4     |

ID = infectious disease, UC = urgent care, MAb = monoclonal antibody, IV = intravenous, RN = registered nurse. Source: Intermountain Healthcare.
Under the EUA criteria, approximately 27% of patients with Covid-19 would be potentially eligible for monoclonal antibody therapy; however, the supply of medication allotted to our state by the U.S. Department of Health and Human Services was only sufficient to treat 2 to 3%.

The MAb Squad providers then used this daily “e-screened” list of patients to review clinical records for eligibility, proactively contacted candidate patients, and provided one-on-one shared decision-making for patients over the phone. Patients who were deemed ineligible over the phone for treatment were provided self-care advice or triaged for advanced care needs, while those interested and eligible were referred to the nearest infusion site. The daily huddle, a part of Intermountain Healthcare’s Operating Model, also allowed for flexibility and communication of up-to-date information, such as the number of patients with Covid-19 an infusion center could accommodate as staffing and numbers of available chairs fluxed. We also set up a referrals pathway open to community providers as well as patients themselves (Figure 1). This pathway allowed access for people who had been tested outside of our system or who were not captured by the e-screening process. A group email address was established and published on the state public health website. MAb team members checked the inbox several times per day.

Educating Patients and Shared Medical Decision-Making

Because bamlanivimab and casirivimab-imdevimab had not yet received full FDA approval, we wanted to ensure that patients were appropriately educated and counseled prior to infusion. Traditional in-office visits could not provide this service efficiently, so we chose a telehealth model. Initially, a single infectious disease specialist within the group confirmed risk scores and engaged in the informed consent discussion with patients by phone. This created too large a bottleneck on the basis of patient volumes, so additional providers were recruited via a redeployment request from elsewhere in the organization. Language interpretive services for more than 30 different languages were available as needed.

Selecting Cost-Effective Infusion Sites Without Compromising Non-Covid-19 Care

Because MAb therapy must be given via intravenous (IV) infusion, we initially identified four potential settings that could be used to safely administer an outpatient infusion of these medications: home health nursing, EDs, hospital-based infusion centers, and urgent care clinics.

Because of the rare but important risk of anaphylaxis and the relative uncertainty about overall tolerability early on, we decided not to pursue MAb infusion by home health services.

Although widely located, EDs were not ideal for a rapid rollout because of issues around cost-effectiveness and high surge-phase Covid-19 volumes that limited available ED resources.
The infusions require personnel to monitor each patient for a minimum of 90 minutes, including the infusion time and an observation period afterwards.

Hospital-based infusion centers were an obvious choice for Covid-19–related MAb infusions because their personnel were already familiar with administering MAb treatments for other conditions. However, infusion centers serve a large nonmodifiable population of patients with oncology and autoimmune conditions. This largely immunocompromised clientele posed a significant infection control concern given that patients with Covid-19 eligible for MAb therapy at these sites were still contagious. Infusion center leadership developed creative cohorting strategies, such as clustering patients without Covid-19 at select infusion centers, creating separate isolated treatment rooms for patients with Covid-19, and adjusting infusion schedules to accommodate patients with Covid-19 receiving MAb in the afternoons after all patients without Covid-19 had left the facility.

Despite these innovations, the number of infusion centers available for providing Covid-19 MAb care was inadequate to meet the number of MAb-eligible patients or to address geographic access.
The solution was to develop infusion capability at select urgent care clinics across the system. Urgent care clinics were good options for several reasons.

First, Intermountain operates a large network of 31 urgent care clinics that are within 10 minutes of 90% of the state’s population and have operating hours 7 days a week. The program selected nine urgent care sites to supplement the geographic footprint of the hospital-based infusion centers, which are also typically not open on weekends. Second, urgent care clinics already provide some infusion services and have been found to be cost-effective for this purpose, and nurses at many of the sites had infusion experience that facilitated just-in-time training. Finally, urgent care volumes had diminished during the pandemic, allowing for the capacity to perform infusions safely at nonpeak times during the day.

**Shifting Strategies with Shifting Demands**

As the community transmission began to decline in the early spring of 2021, a few new challenges required our program to shift strategy to match available resources with demand.

First, volumes at the walk-in urgent care clinics began to return to busy prepandemic levels, and some sites intermittently became unavailable for scheduling same-day infusions because of the demands for clinic space. This lack of availability became problematic because we had chosen our initial group of urgent care sites to achieve geographic equity. As availability decreased, patients would sometimes have to travel more than an hour to alternative locations, threatening patient experience, access, and equity for those without reliable transportation.

> Because bamlanivimab and casirivimab-imdevimab had not yet received full FDA approval, we wanted to ensure that patients were appropriately educated and counseled prior to infusion. Traditional in-office visits could not provide this service efficiently, so we chose a telehealth model.

Leveraging great administrative support and a strong urgent care representation on the team, we simultaneously reduced the number of infusion appointments available each day at each urgent care clinic and expanded into additional urgent care locations. This expansion allowed creative supply-demand matching within the urgent care workflow while still maintaining local availability for patients. Similarly, we worked with ED leadership to develop point-of-care infusion capability in centers within the densely populated Salt Lake metropolitan area, with plans to scale incrementally throughout the system. This strategy reduces stress on the existing MAb infusion network and captures additional patients who are often at the end of their window of eligibility. Finally, as tolerability and real-world rates of infusion reactions have become much better understood, we have begun work to bring MAb infusion to the home care setting, starting with a pilot program.

Second, as total state-level case counts began to decrease, several rural and more sparsely populated areas started showing a disproportionately high number of Covid-19 cases. To meet focal
geographic demands, individual strategies were used for specific locations where we needed infusion capacity.

In one community that needed additional weekend availability of MAbs, we worked with local leadership to enlist the services of the local on-call peripherally inserted central catheter (PICC) team for the Intermountain-affiliated community hospital. The PICC nurse could open the infusion center and run at least one MAb infusion each weekend morning without sacrificing their availability during the rest of the day for inpatients needing PICC access.

In another community, the local urgent care and outpatient infusion center were both too small to safely accommodate patients with active disease, but the next nearest infusion center from the first phase of our program was an hour away. The infusion center managers arranged with the local community hospital for patients with Covid-19 to receive their infusions in beds normally allocated for inpatients.

As community transmission rates decreased and the need for MAb providers to resume non-Covid-19 care arose, the redeployed MAb Squad was reduced proportionally. However, because of the significant logistical challenge of coordinating referrals to available locations, it was determined that shifting to a conventional model in which any prescriber could order MAb infusion was impracticable. A core group of five urgent care-based MAb providers was therefore retained to continue screening, patient contact, and referral coordination. They also provided clinical consultation for adverse reactions and for clinical questions originating from point-of-care providers in EDs.

Finally, in late June 2021, the HHS issued a statement citing lack of efficacy of bamlanivimab-etesevimab against some of the emerging variants, and it halted distribution of this drug. Initially, bamlanivimab-etesevimab and casirivimab-imdevimab were being used somewhat interchangeably, and, for ease of staff training, most of our urgent care sites were stocked solely with bamlanivimab-etesevimab, while the hospital infusion centers and other sites carried casirivimab-imdevimab. The new variant data required us to switch all of our urgent cares to casirivimab-imdevimab. Working with the supply chain and our urgent care clinic managers, our pharmacy team was able to communicate with nursing, distribute the new drug, reprogram the infusion pumps, and revise the electronic medical record order set in a smooth, coordinated manner so that all sites were aligned on the same day. At this time, our program uses only casirivimab-imdevimab.

**Current Funding**

Since the peak of the pandemic, we have been able to operationalize Covid-19 MAb infusion services into existing infusion center and urgent care revenue streams. While the cost of the drug continues to be covered by the federal government, the infusion charges are billed in the usual way through patients’ private health insurance. For uninsured patients, Intermountain covers costs with funding from the Health Resources and Services Administration (HRSA) that is administered via a voucher program, the framework for which existed prior to the pandemic, because Intermountain is the largest charity care provider in a state without a robust public safety net hospital system. The
MAb Squad providers continue to operate as needed on an hourly basis within our system’s employed medical group framework for Covid-19 redeployment.

“Because of the rare but important risk of anaphylaxis and the relative uncertainty about overall tolerability early on, we decided not to pursue MAb infusion by home health services.

In our value-based care operating model (in which Intermountain is at risk for a large number of patients insured by SelectHealth, our integrated health plan), we see substantial cost savings from each Covid-19 admission prevented. For example, approximately 22.7% of all MAb infusions (295 of 1,300) have been performed on patients covered by SelectHealth. Recent analysis of our clinical outcomes demonstrated a number needed to treat of about eight patients in order to prevent one ED visit or hospital admission. SelectHealth cost for the average Covid-19 admission is approximately $24,000; thus, for each dose of MAbs infused in SelectHealth recipients, we see a raw cost savings of about $2,411 per infusion. After factoring in per-infusion charges of approximately $510 and hourly costs for MAb Squad providers, we estimate that the net savings related to hospitalization prevented alone is between $1,292 and $1,895 per patient infused: a total of $381,060 to $558,938 since program launch.

Metrics

Over 2 weeks, staff were trained at 16 infusion sites, comprising seven outpatient infusion centers and nine urgent care clinics, providing coverage for most of the state (Figure 2). Average infusion capacity at these sites was 30 patients receiving MAb each weekday and about 18 patients receiving MAb per day on weekends and holidays. Most eligible patients were screened and scheduled for infusion within 3 days of receiving their Covid-19 test result.

Our program reached peak volumes in December 2020 and January 2021, which also coincided with the peak of the pandemic in Utah. In December, 3,759 patients were e-screened, resulting in 255 infusions. In January, 3,766 patients were e-screened, resulting in 465 infusions (Figure 3).

On the basis of a convenience sample of screening logs, the median number of candidates who were identified per day using the e-screening process was 63 (range 12–132), of whom virtually all were reviewed each day by members of the MAb team. From the e-screening list, 13.9% were scheduled for infusion (Figure 4).

Those who were excluded from the sample included 38.2% whose e-screen overestimated their actual risk score (because of factors such as their no longer having the high-risk condition indicated in their record), 26.7% who were ineligible for other clinical reasons (e.g., being outside of the 7-day treatment window, having an increased oxygen requirement over their pre-Covid-19 baseline, or needing inpatient care), 19.3% who were unable to be reached by phone, and 1.3% who were not interested or declined MAb treatment.
FIGURE 2

Map of Monoclonal Antibody Infusion Sites

Source: Intermountain Healthcare
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society
The characteristics of patients screened over this time frame are given in Table 2. Communities of color, defined as non-white race and/or Latinx ethnicity, were overrepresented in our screened patients, with 28%; by comparison, approximately 22% of the population of Utah belongs to a community of color.\(^9\) Approximately 6% of e-screened patients came from rural counties, defined as those without metropolitan or micropolitan centers.\(^10\) This matched the general population of Utah.

We studied provider and patient self-referral patterns in a convenience sample of our screening logs. The median number of referrals received per day was four (range 0–15). Of those referrals, 82.4% came from medical providers and 17.6% from patients themselves. A total of 57% of provider referrals were scheduled for infusion compared with 47% of patient self-referrals. Overall, 55.6% of referrals were scheduled for infusion. The breadth of referrals included 83.6% from within our integrated health care delivery system and 16.4% from external, nonaffiliated providers. Over our 2-month sample period, we received referrals from 67 unique providers across eight specialties.
Outcomes of E-Screened Patients

Outcomes of e-screened patients with Covid-19 treated by the monoclonal antibody team at Intermountain Healthcare.

| Category                                      | Percentage |
|-----------------------------------------------|------------|
| Patients whose e-screened risk score was inaccurately high | 38.2%      |
| Patients ineligible for other clinical reasons | 26.7%      |
| Patients not interested/declined              | 13.9%      |
| Patients unable to be reached                  | 19.3%      |
| Patients from list scheduled for infusion      | 1.3%       |

Source: Brandon J. Webb and Daniel Davie

NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Table 2. Characteristics of E-Screened Patients

| Characteristic                          | Value                   |
|----------------------------------------|-------------------------|
| Risk score, median (IQI)               | 9 (8–11)                |
| Number of comorbidities, median (IQI)  | 4 (3–5)                 |
| Age, mean (SD)                         | 62.0 (15.1)             |
| Male (%)                               | 56.8                    |
| Communities of color (%)               | 28.3                    |
| Patients from rural counties (%)       | 6                       |

IQI = interquartile interval, SD = standard deviation. *Rural counties are defined as those without metropolitan or micropolitan statistical areas. Source: Intermountain Healthcare.
Where to Start

For organizations that are considering starting an outpatient MAb program, we suggest several focus areas:

- Use what is available to you. Urgent care clinics and hospital-based infusion centers may be available. In other systems, other settings such as specialty clinics or procedural centers, where staff are comfortable with IV medications and treating allergic reactions to medications, may be excellent options. In other systems, EDs may be a good fit if volumes, resources, and space allow.

- Buy-in from leadership is crucial. It is impossible to build bridges between traditionally siloed departments or clinics without support from a decision-maker who understands the big picture and has the authority to resolve concerns. Involving leadership early on will help limit delays.

- Keep it patient centered. What will the patient’s experience be, and how can you make it easy for them? How will the program address equity and health care access disparities?

Need for State-Level Leadership and Coordination with Health Care Organizations

The Utah Crisis Standards of Care Scarce Medications Allocation Committee provided a key interface between state officials and the organizations and experts at the front line of care delivery, and this collaboration led to the development and coordination of a data-driven strategy for delivering Covid-19 MAbs. The state managed a website that included both information about the treatments and how to access them and a central place where eligibility criteria could be kept transparent and up to date. Because of this state-level committee and its collaborative approach, Utah created a strong framework within which Intermountain could operate in delivering MAbs to patients with Covid-19.

The Role of the Integrated Medical System

Intermountain’s structure as an integrated health care system helped overcome barriers to rapid deployment of our program. First, investments in a single electronic health record, data warehouse, and informatics support allowed computerized calculation of the risk score and dramatically improved efficiency, allowing clinical providers to spend their time advising patients.

Second, having an aligned physician group and employed APPs simplified the administrative task of redeploying providers to work on this project. No new credentialing was required, and contract addenda could be handled succinctly for participating providers.

“Since the peak of the pandemic, we have been able to operationalize Covid-19 MAb infusion services into existing infusion center and urgent care revenue streams.”
Similarly, the redeployment process allowed for the recruitment of appropriate numbers of providers from settings such as urgent care clinics at times when patient volumes were reduced because of the pandemic.

Third, having a service line model allowed for the rapid creation of infusion sites across our entire health care system’s geography. After an initial pilot urgent care site was successful, the clinic practice manager from that location worked with the service line medical and administrative directors to identify and train additional sites under a standardized protocol. Outpatient infusion centers were brought online in a similar fashion, with decisions made regionally rather than at each individual site.

Finally, our organizational commitment to population health aligned well with shifting the paradigm for our MAb program from a traditional health care delivery model to a public health endeavor. As an organization with health care delivery infrastructure spanning the state and including some communities in neighboring states, we made every effort to get patients treated as long as they met Utah’s criteria for eligibility, regardless of ability to pay or whether or not a patient had ever been seen previously within our health care system. Our goal was to prevent Covid-19-related hospitalizations, thereby offloading all overtaxed regional and local health care systems, not just our own. From a public health perspective, by using a government-provided medication in conjunction with HRSA funding, we were able to design a patient identification strategy that focused on equity and breadth, rather than on affiliation or payer status. The initial potential benefit of a release valve on overloaded inpatient services and ICUs was reason enough for engaging in this project.

**Next Steps**

We see two main next steps for our program. First, we must better understand the true efficacy of these drugs. As severe acute respiratory syndrome coronavirus 2 becomes more endemic and as the HHS drug distribution program gives way to a more traditional drug-purchasing model, we must be able to see how these treatments fit into a broader health care equation. We will also need these data to help us answer questions around the sustainability of our program. When and how should we transition to a more conventional care paradigm?

Second, we must continue to expand mechanisms that support access and equity. Social determinants of health have already played a major role in this pandemic’s impact on certain communities, and they will continue to do so as long as there are inadequate tools for addressing them. By identifying and reducing barriers to treatment, our MAb program could continue to serve as an important strategy for mitigating impacts of Covid-19 until better upstream solutions are implemented.

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