BrightInsight

WHITE PAPER

Remote patient monitoring to simplify risk evaluation and mitigation strategy (REMS) protocols

Digital monitoring for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS)

Cell therapy and immunotherapy are at the forefront of treatment for many cancers. Treatments like CAR-T cell therapy are quickly becoming the standard of care for blood cancers like leukemia—and with incredible results. According to the American Society of Hematology, CAR-T therapy, which takes cells from a patient and genetically modifies them with an artificial, cancer-targeting cell, has demonstrated remission rates of 76%.[1]

Yet these game-changing therapies aren't without their complications. Cytokine release syndrome (CRS) is the most common acute toxicity following CAR-T therapy, occurring in between 37% and 93% of patients across different studies.[2] The majority of patients only experience minor CRS side effects when detected early—fever is almost always the first sign. Flu-like symptoms can develop within the first week of treatment and resolve within eight days.

Thirty-three percent of patients experienced immune effector cell-associated neurotoxicity syndrome (ICANS)[3] which can present more serious side effects, like confusion, language disturbance, motor weakness, seizures and headache. Worse yet, respiratory distress and multi-organ failure are possible.

What makes CRS and ICANS particularly hard to treat is that care providers simply can't predict who will be affected by these potentially dangerous conditions or how likely it is to be one of the severe cases—which can take a tremendous emotional toll on patients who are already fighting cancer.

This presents a serious challenge for biopharma companies: cell therapies are an incredible advancement in the treatment of blood cancers, yet the potential for serious side effects can't be overlooked. How can pharma companies leverage patient apps, connected devices and remote patient monitoring to decrease the risk of complications for patients on these life-saving cell therapies?

In this white paper, we'll explore how digital remote patient monitoring can simplify the process for clinicians by providing patients and caregivers with the tools to unlock early detection, the most powerful approach to decreasing complications caused by CRS and ICANS.

1 https://www.hematology.org/newsroom/press-releases/2023/a-promising-outlook-car-t-cells-improve-patient-quality-of-life#:~:text=Overall%2C%2076%25%20of%20patients%20achieved,follow%20up%20for%20the%20study.
2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8671280/#:~:text=The%20CRS%20is%20the%20most,and%2093%25%20across%20different%20studies.
3 https://www.hematology.org/newsroom/press-releases/2023/a-promising-outlook-car-t-cells-improve-patient-quality-of-life#:~:text=Overall%2C%2076%25%20of%20patients%20achieved,follow%20up%20for%20the%20study

Challenges in anticipating and treating CRS and ICANS

As cell therapy becomes ubiquitous, healthcare providers and hospitals are rarely taken by surprise when a patient develops CRS or ICANS. These side effects are expected in all patients. What's not predictable is how severe it will be and for which patients. That means that every event has to be treated with the utmost urgency—an unsustainable and non-scalable dilemma that ultimately limits the quality of care patients receive and limits the quantity of therapy made accessible to patients.

Here are a few of the key challenges in treating these two conditions.

- **Burden of care:** Current monitoring processes, both inpatient and outpatient, are highly manual, inconsistent and largely dependent on caregivers and patients themselves. Within a clinic or hospital setting, monitoring relies on analog tools (e.g., blood pressure and temperature readings), which puts a heavy burden on nursing staff. This means that some hospitals can only administer this therapy to a couple patients per week.

  Once patients are discharged, the burden on the patient and their caregiver is immense—it requires 24/7 monitoring for early signs of toxicity for up to 30 days. This can create significant stress and emotional burden in families already dealing with cancer.

- **Uneven access to care:** The demand for CAR-T and other therapies continues to grow, yet because of the monitoring requirements, few centers are certified to administer immunotherapy treatments. That means many patients must travel long distances to receive care, then stay near the clinic until their toxicity risk has diminished.

- **Inconsistent monitoring:** Because the burden of manual in-patient monitoring is so high, early signs of toxicity are often overlooked. This increases patient risk, leading to hospital re-admittance and ICU referrals and further burdening an overtaxed healthcare system.

- **Increased costs:** Prolonged inpatient and ICU stays cause costs to skyrocket, both for payers and in out of patient costs to patients and their families.

In their own words

Patients and caregivers on the challenges of monitoring for neurotoxicity

> **I was afraid to go to sleep or have any heavy meds** [post treatment]. I wanted–needed–to feel alert to watch for symptoms."
>
> – Patient

> I took my temperature and blood pressure when the home health nurse wasn't there. In the morning and at night. I wrote it down, and after a week, would email or call and report them, or would **take a screenshot or picture and send it to the nurse and the oncologist.**"
>
> – Patient

> **I felt overwhelmed. It was 30 days of 24/7 monitoring.** My role as the caregiver was to monitor for neurotoxicity and take his temperature three times a day. We taped the printout the nurse had given us near his bed. I had to Google a lot of it. There was always some anxiety. **I was most worried about neurotoxicity.** The doctors said it was irreversible with more long-term damage."
>
> – Caregiver

BrightInsight's CRS + ICANS RPM companion app

Empower patients with a seamless at-home monitoring system

Our digital companion app eases the burden of ongoing monitoring for cancer patients and caregivers, and brings much needed peace of mind. Integrated devices and guided assessments let patients know when to contact their care team, and educational resources help with management of less urgent symptoms. By reducing time in-hospital and replacing manual around the clock monitoring, patients can put their focus where it should be: rest and healing.

App features

- Caregiver app directly linked to the patient app
- Personalized REMS educational materials and self-care instructions to manage non-emergent side effects, such as nausea and dehydration
- Integrates with connected devices for CRS detection to automatically track biometrics, including:
  - Temperature
  - Heart rate
  - Blood pressure
  - Oxygen saturation
- Notifications for vitals monitoring to ensure early CRS detection, including guided alerts to see a provider or go to ER
- Periodic biometric trend reports for patient and caregiver that can be easily exported to provider
- Caregiver-directed ICE questionnaire conducted in app, with corresponding ICANS grade provided after completion
- Quality of life surveys
- Simple in-app REMS enrollment
- Digital wallet card to ensure ready access for patient and caregiver

Benefits for the healthcare system

- Remote at-home monitoring reduces hospital stays and increases the number of patients who can benefit from CAR-T therapy
- Simplifies in-hospital monitoring for nursing staff
- Increases early detection of CRS and ICANS, lowering risk of serious complications and reducing system impacts
- Increases HCP confidence in CAR-T therapies
- Generates consistent real-world data collection
- Creates value and differentiation for biopharma companies in an increasingly crowded sector

Want to learn more about remote patient monitoring for CRS and ICANS?