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Quality Improvement Strategies to Optimize Outpatient Step-Up Dosing for Elranatamab in Relapsed/Refractory Multiple Myeloma

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Introduction

Advances in cancer treatment have led to therapies becoming more personalized and targeting specific disease pathways. Although these innovations improve patient outcomes, the growing complexity of cancer care creates challenges in care coordination, patient counseling, advanced monitoring, and management of treatment-related toxicities. As a result, quality improvement (QI) and quality assurance (QA) have become critical to ensure that all patients with cancer receive consistent, evidence-based, and high-quality care.

Improvements in cancer care are often driven by two primary approaches: QI and QA. QI is a continuous process aimed at achieving measurable improvements in healthcare services. It emphasizes fostering a culture of learning, innovation, and improvement, encouraging proactive identification and resolution of care delivery gaps, promoting employee engagement and empowerment, and building trust within the healthcare system, all directed toward improving care quality. In parallel, QA is a proactive and continuous process focusing on maintaining high standards in healthcare delivery through ongoing monitoring of processes and outcomes. Both initiatives are particularly relevant to oncology care, where they help address challenges such as managing complex treatment regimens, reducing variability in care delivery, and ensuring patient-centered outcomes. QI and QA initiatives can be implemented through structured frameworks such as Plan-Do-Study-Act, Lean, or Six Sigma, or through flexible, ad hoc approaches tailored to specific clinical and operational needs.[1,2]

Commentary by E. Bridget Kim, PharmD, BCPS, BCOP: *For us, QI and QA projects mean taking a structured, data-driven approach to how we deliver care. It's about standardizing processes, improving safety, and ensuring everything we do aligns with the best available evidence.*

Commentary by Diana Cirstea, MD: *When you think about QI and QA, the key concepts are standardizing workflows, pathways, and embedding protocols that incorporate newer drug indications in a safe and practical way.*

QI and QA initiatives in healthcare settings, including oncology, have demonstrated remarkable effects on patient outcomes, regardless of the method used for exploration and implementation. For instance, a study involving 142 patients implemented a QI intervention to standardize discharge procedures that resulted in a mean decrease of 7 days in the scheduling of follow-up appointments with hematologists and oncologists.[3] In addition, multiple QI initiatives at the Mayo Clinic, including the implementation of enhanced post-surgery recovery protocols and the adoption of evidence-based practices to guide perioperative management in both benign and oncologic gynecologic surgery, have shown improved patient outcomes. Reported improvements included improved outcomes in pain control, return of bowel function, length of stay, and costs. These examples highlight how QI/QA initiatives can identify care gaps, improve resource utilization, and ultimately enhance patient outcomes.

Commentary by E. Bridget Kim, PharmD, BCPS, BCOP: *What we learned from the QI/QA projects is foundational to achieving optimal outcomes for all our patients. You can have an effective therapy, but you won't get its full benefit without the right systems in place.*

The benefits of QI/QA processes are well established in healthcare and oncology. QI/QA processes are particularly important in blood cancers such as multiple myeloma (MM) due to the complex and often prolonged nature of treatment regimens, frequent monitoring requirements, and the need to manage therapy-related toxicities, which can significantly impact patient outcomes and quality of life.[4]

This article examines how QI/QA processes at Massachusetts General Hospital (MGH) have improved care delivery and patient experience in MM, with a focus on integrating bispecific antibodies such as elranatamab into clinical practice. It also reviews supporting clinical evidence and practical considerations for treatment administration and adverse-event (AE) management of elranatamab.

Multiple Myeloma

The treatment landscape for MM has expanded with the introduction of immunomodulatory drugs (IMiDs), proteasome inhibitors, and immune-based therapies, such as anti-CD38 monoclonal antibodies (mABs), significantly improving survival outcomes.[5] In patients with newly diagnosed MM, phase 3 trials have shown that adding a CD38-targeting antibody to standard frontline therapy enhances clinical responses, and is generally tolerable, highlighting the importance of incorporating immune-based therapy early in treatment.[6-8] While these results underscore the benefits of intensive upfront therapy, many patients eventually relapse, and those with relapsed/refractory MM (RRMM) face limited treatment options due to complex clinical features, prior refractory status, and cumulative exposure to multiple therapies.[9]

Real-world data highlight poor outcomes in patients with heavily pretreated RRMM. The prospective LocoMMotion study in triple-class–exposed patients reported a median progression-free survival (PFS) of 4.6 months; among those receiving subsequent lines of treatment, PFS was 10.8 months.[10] This study highlights the need for new therapies that provide durable responses in heavily pretreated patients. Triple-class–refractory patients who have progressed after treatment with IMiDs, proteasome inhibitors, and anti-CD38 mABs represent a particularly high-risk group with limited options for disease control.

Novel immunotherapies, including chimeric antigen receptor T-cell therapy and bispecific agents, have shown clinical activity in patients with RRMM after multiple prior lines of therapy.[11] Elranatamab, a B-cell maturation antigen (BCMA)-directed bispecific antibody approved for the treatment of adult patients with RRMM who have received at least 4 prior lines of therapy, including a PI, an IMiD, and an anti-CD38 monoclonal antibody, has demonstrated clinical activity and a manageable safety profile.[12,13]

Commentary by Diana Cirstea, MD: *When considering patients who could benefit from elranatamab, a bispecific antibody, both disease biology and patient comorbidity profiles are key factors to evaluate. From a disease perspective, ideal candidates are typically those who are triple-class–refractory, having been treated with immunomodulatory agents, proteasome inhibitors, and CD38 monoclonal antibodies, and have subsequently progressed on these therapies. Elranatamab offers a promising solution for such heavily pretreated patients. Moreover, elranatamab has demonstrated both efficacy and tolerability in elderly patients and those with significant comorbidities, supported by its subcutaneous administration and predictable safety profile.*

Although the bispecific antibodies have demonstrated meaningful clinical efficacy in RRMM, their use is associated with unique challenges that require careful consideration. Distinct toxicities, including cytokine release syndrome (CRS), infections, neurotoxicity, and cytopenias, have been consistently reported.[5] Beyond safety concerns, outpatient administration of bispecific antibodies introduces logistical complexities, particularly during the first 2 step-up doses, which require early recognition and management of AEs.[14] Healthcare teams must be adequately trained to identify symptoms of CRS and other toxicities early, and patients need clear guidance on when and how to seek medical attention. In this context, understanding the clinical profile of elranatamab, including its efficacy, safety considerations, and practical aspects of administration, is critical for integrating AE management, optimizing operational workflows, and ensuring continuous QI approaches to improve patient outcomes.

Overview of Elranatamab

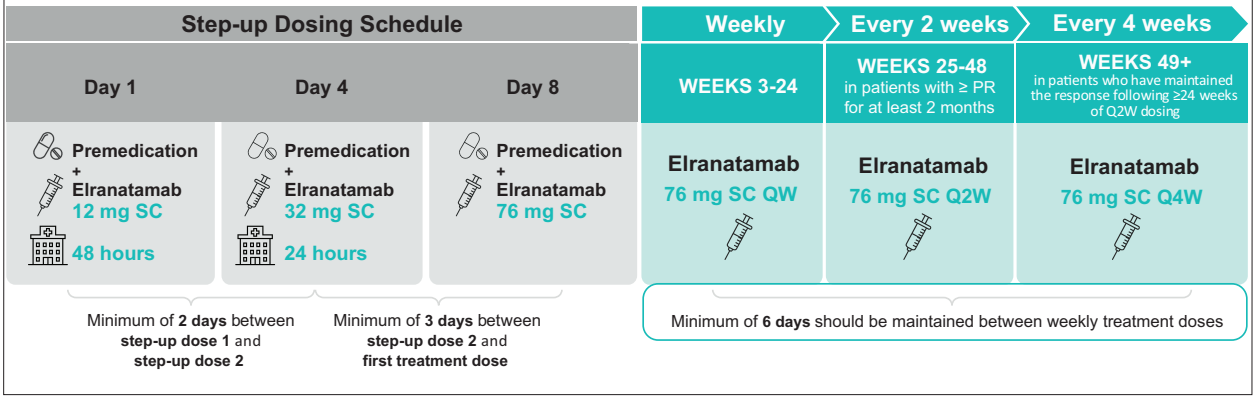
Elranatamab is a bispecific antibody that targets BCMA, highly expressed on myeloma cells, and CD3 on T cells.[15] By binding to both BCMA and CD3, elranatamab redirects cytotoxic T cells toward myeloma cells, inducing T-cell–mediated cytolysis.[15] Activation of T cells leads to cytolysis of BCMA-expressing plasma cells and triggers the release of proinflammatory cytokines, which may result in AEs such as CRS and immune effector cell–associated neurotoxicity syndrome (ICANS).

Clinical Data: MagnetisMM-3 Study

The MagnetisMM-3 study (NCT04649359) is an open-label, multicenter, single-arm, phase 2 trial designed to evaluate the efficacy and safety of elranatamab in patients with RRMM. Elranatamab was administered subcutaneously at a dose of 76 mg once weekly in a 28-day cycle following a step-up dosing schedule: 12 mg on day 1, 32 mg on day 4 and 76 mg on day 8 of cycle 1 to mitigate the risk associated with CRS, as shown in **Figure 1**. Premedication with acetaminophen, diphenhydramine, and dexamethasone was required before each step-up dose and the first full dose to reduce the risk of AEs. Patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

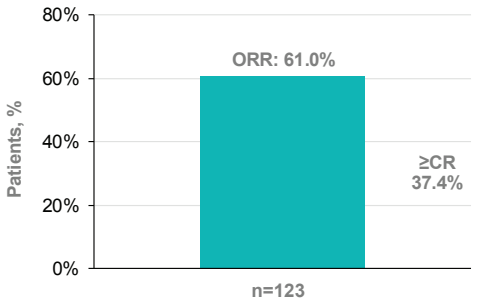
The primary endpoint of the MagnetisMM-3 study was overall response rate (ORR). Among BCMA-naïve patients, after a median follow-up of 33.9 months, a clinically meaningful improvement was observed; the ORR was 61.0% with 37.4% of patients achieving a complete response or better (**Figure 2**).

Figure 1: Dosing Schedule for Elranatamab[16]



Treatment-emergent adverse events (TEAEs) were reported in all participants. Grade 3 or 4 TEAEs occurred in 71.5% of patients, with the most common (≥25%) including infections (70.7%; 41.5%, grade 3-4), neutropenia (49.6%; any grade, 3-4), anemia (48.8%; 37.4%, grade 3-4), and thrombocytopenia (32.5%; 23.6%, grade 3-4). CRS occurred in 57.7% of patients, and all cases were grade 1 to 2. Other frequent TEAEs included diarrhea (46.3%; 4.9%, grade 3-4), fatigue (38.2%; 4.1%, grade 3-4), decreased appetite (34.1%; 0.8%, grade 3-4), and pyrexia (33.3%; 4.1%, grade 3-4) (**Figure 3**). A post-hoc analysis of a US subgroup (n=47) demonstrated consistent efficacy and safety outcomes as the primary analysis.[18]

Figure 2: MagnetisMM-3 Efficacy Data[17]



*Data cutoff date was September 10, 2024.

Figure 3: MagnetisMM-3 Safety Data[15,17-20]

Most Common TEAEs (≥25%), n (%)*,†

n (%)	Any grade (n=123)	Grade 3 or 4 (n=123)
Any TEAE	123 (100)	88 (71.5)
Hematologic		
Neutropenia	61 (49.6)	61 (49.6)
Anemia	60 (48.8)	46 (37.4)
Thrombocytopenia	40 (32.5)	29 (23.6)
Lymphopenia	33 (26.8)	31 (25.2)

n (%)	Any grade (n=123)	Grade 3 or 4 (n=123)
Nonhematologic		
Infections‡	87 (70.7)	51 (41.5)
CRS	71 (57.7)	0
Diarrhea	57 (46.3)	6 (4.9)
Fatigue	47 (38.2)	5 (4.1)
Decreased appetite	42 (34.1)	1 (0.8)
Pyrexia	41 (33.3)	5 (4.1)
Cough	36 (29.3)	1 (0.8)
Hypokalemia	34 (27.6)	16 (13.0)
Nausea	33 (26.8)	0
Injection site reaction	33 (26.8)	0

*Data cutoff date was September 10, 2024; median follow-up by reverse Kaplan-Meier method was 33.9 months (range, 33.4-34.6). †TEAEs according to the Medical Dictionary for Regulatory Activities v27.0 and Common Terminology Criteria for Adverse Events v5; any-grade TEAE reported in ≥25% of patients; severity of CRS and ICANS was assessed according to the American Society for Transplantation and Cellular Therapy criteria. ‡Infections include preferred terms in the system organ class of infections and infestations.

Commentary by Diana Cirstea, MD: *Elranatamab has demonstrated the ability to induce rapid responses, which is critical for stabilizing sick and less-fit patients. In clinical practice, biochemical responses may be observed shortly after completion of step-up dosing, and the high rates of MRD negativity further underscore its therapeutic efficacy and prognostic relevance. With appropriate management of step-up–associated low-grade CRS, as well as infections and cytopenias, patients often experience improvements in quality of life.*

In conclusion, elranatamab showed a high ORR with a manageable safety profile for heavily pretreated BCMA-naïve patients with RRMM, including those in the US subgroup. Transitioning to every-4-week dosing may also enhance safety and convenience while maintaining efficacy.

Quality Improvement and Assurance at MGH

Identifying and Implementing QI/QA Initiatives

At MGH, the QI/QA initiatives provide a structured, data-driven approach for standardizing workflows and pathways, and embedding evidence-based practices into routine care, particularly for complex therapies, such as bispecific antibodies. This ensures that care processes are safe, efficient, and adaptable to real-world needs. QI/QA efforts include developing protocols that incorporate newer drug indications and support consistent outpatient administration based on observed safety profiles.

In developing outpatient step-up dosing protocols for bispecific therapies such as elranatamab, MGH evaluated models from other centers and integrated MGH-specific data to address local area needs. Key focus areas included safety, outcomes, logistics, and scalability to community and satellite oncology sites. Additionally, operational constraints such as limited hospital bed availability guide decisions on whether patients are better suited for inpatient or outpatient care, particularly for bispecific therapies like elranatamab.

Commentary by Sarah O'Neill, PharmD, RPh, CMPP™: *QI projects help bridge the gap between tightly controlled clinical trials and the variability of standard care. Clinical trials follow strict protocols, while real-world practice allows more flexibility in dosing, scheduling, and management. The outpatient step-up–dosing QI project with elranatamab was valuable because it balanced both. A clear protocol for eligibility, monitoring, and CRS escalation ensured safety, while still allowing flexibility to reflect real-world practice, making the approach both practical and impactful.*

Updating QI/QA Processes

QI/QA workflows at MGH are updated in response to emerging clinical evidence, new drug indications, guideline changes, or evolving safety signals. Workflows may also be adapted to support novel dosing modalities such as elranatamab's outpatient bispecific step-up dosing or to support potential new dosing combinations in earlier lines of therapy such as elranatamab plus anti-CD38 monoclonal antibodies. Safety monitoring also drives refinement of protocols and workflows. For example, dexamethasone dosing for CRS prophylaxis was adjusted after AEs including insomnia and hypertension were identified through detailed, symptom-specific assessments. However, reduced dosing of dexamethasone proved less efficacious, necessitating a return to the original regimen. Comprehensive documentation and real-time data collection enable identification of AE patterns and support precise, timely updates. Unlike clinical trials, QI/QA initiatives allow rapid, iterative modifications through frequent multidisciplinary collaboration among clinicians, nurses, and pharmacists, ensuring operational efficiency, patient safety, and continuous improvement. However, long-term sustainability requires adequate resources and dedicated personnel to support ongoing data review and implementation of changes.

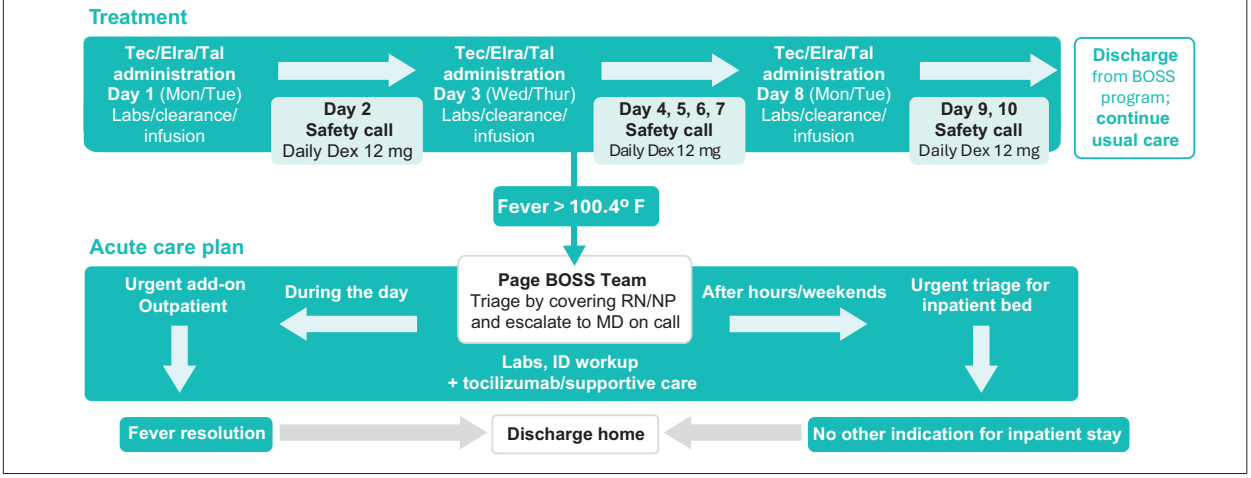
Commentary by E. Bridget Kim, PharmD, BCPS, BCOP: *The strength of QI/QA projects lies in their adaptability, allowing us to implement changes quickly compared to the rigidity of clinical trials. Through frequent team meetings, we address challenges like workflow bottlenecks and evolving safety signals in real time, ensuring processes are updated efficiently and quickly.*

Outpatient Administration Protocol

Bispecific antibody therapies have traditionally required inpatient monitoring to manage risks such as CRS and ICANS. While inpatient step-up dosing effectively mitigates these risks, it introduces logistical and financial barriers that can limit access for patients with RRMM. To address these challenges, MGH implemented the Bispecific Outpatient Safe Step-Up (BOSS) program as a QI initiative. This structured outpatient step-up dosing approach is designed to support safe outpatient administration of bispecific therapies, including elranatamab. Drawing on clinical trial data, insights from other institutions, and MGH-specific experience, it provides a framework for expanding outpatient care while maintaining established safety standards.

The BOSS program integrates dexamethasone prophylaxis, a structured outpatient step-up dosing workflow, safety monitoring, and defined acute care pathways for managing CRS, neurotoxicity, and other AEs. The workflow is illustrated in **Figure 4**. The BOSS program aids guiding the identification of patients who are appropriate for either inpatient or outpatient administration of elranatamab based on clinical factors (eg, CRS risk and disease burden) and nonclinical considerations (eg, availability of caregivers, adherence to monitoring and medications, and proximity to the treatment center). In practice, not all patients receiving elranatamab require intensive inpatient monitoring; some patients may be suitable for outpatient step-up dosing, which can help preserve inpatient bed capacity for more acutely ill patients.

Figure 4: BOSS Program Workflow at MGH



Developed through a multidisciplinary approach, the BOSS program prioritizes proactive care coordination through streamlined workflows tailored to the needs of patients receiving bispecific antibodies. Comprehensive patient education, stakeholder engagement, and clearly defined communication pathways support care coordination across settings, enabling use of outpatient treatment options. By reducing barriers to access and lowering healthcare costs, the BOSS program sets a foundation for equitable delivery of immunotherapy while maintaining safety standards.

Toxicity Management and Monitoring Pathways

Toxicity management and monitoring are key parts of cancer care and these processes should be fit for purpose for the institution. At MGH, CRS prophylaxis strategies for elranatamab were adapted specifically for outpatient settings. They developed a practical and scalable approach to CRS prophylaxis, prioritizing outpatient care using dexamethasone over tocilizumab. While tocilizumab required significant logistical resources, including infusion clinic availability and trained staff, dexamethasone offered a more accessible and resource-efficient alternative, especially for community and rural settings. Informed by institutional data, input from other centers, and extensive experience with elranatamab during MagnetisMM trials, MGH incorporated dexamethasone into its BOSS program. A clear escalation protocol was implemented to manage toxicity, ensuring patients and providers understand the steps for addressing symptoms like CRS. Consistent symptom workups, such as fever evaluations, were standardized across providers to ensure comprehensive care and accurate data collection.

Commentary by Kacthary Sanclemente, BSN, RN: *During the critical step-up dosing period, patients are closely monitored through in-person visits and telemedicine to ensure safety and adherence to their medication regimens. This includes regular checks on essential medications, such as dexamethasone and prophylaxis for shingles, as well as other prescribed treatments. If a dose is missed, we guide patients on safely adjusting their schedule and encourage them to document their doses to prevent errors like double dosing. This structured approach provides an additional layer of support, ensuring that patients are well informed and their treatments remain on track.*

Patient Education and Care Coordination

To support adherence to home medications, including CRS and infection prophylaxis, MGH uses standardized educational materials to educate patients and caregivers, and a patient diary to encourage daily medication tracking. During the step-up dosing period, when the risk of CRS and neurotoxicity is highest, patients are monitored through a combination of clinic visits and telemedicine encounters, with follow-up calls providing an additional check on adherence and enabling real-time identification of missed doses. In parallel, a centralized database is used to track adherence, identify gaps, and inform iterative refinements to supportive interventions, integrating education, monitoring, and data review to support safe outpatient management.

Challenges in QI/QA Process Implementation

Implementing QI/QA initiatives for resource-intensive therapies like bispecifics involves complex workflows and requires coordination across multidisciplinary teams. Operational and communication barriers can arise during implementation, making early stakeholder engagement and frequent communication essential for smooth implementation and long-term success. Education and advocacy remain critical components, as ongoing staff training is needed to ensure patient safety and continuity of care. Staffing and resource limitations, such as off-hours coverage requirements and the need for dedicated tools like a 24/7 pager, represent additional barriers toward implementing QI/QA initiatives. Educational gaps and protocol fatigue further challenge implementation, reinforcing the importance of simplifying workflows to improve practicality and usability.

Commentary by Diana Cirstea, MD: *Effective implementation of QI/QA initiatives requires addressing education gaps through constant teaching at various levels. However, overly complex protocols can lead to "protocol fatigue," where workflows become too involved and burdensome. To overcome this, simplifying processes and making them more practical and user-friendly is essential for ensuring consistent adherence and provider comfort while maintaining high-quality patient care.*

Health Equity, Access, and Barriers to Care

MGH's patient population is diverse and has a multitude of socioeconomic factors that play a role in accessing treatment overall and in determining eligibility for outpatient administration of elranatamab. These factors may include language and cultural differences, financial struggles, transportation issues, and lack of 24/7 caregivers. At MGH, efforts are being made to bridge these gaps. For example, MGH is working toward providing translated patient educational materials to support equitable access to care across all cultural backgrounds. Practical and financial support for patients is also sought out from resources such as Blood Cancer United or from MGH's own Caring for a Cure program. Barriers to care, particularly in the ability to administer elranatamab in the outpatient setting, may also stem from lack of knowledge on the healthcare provider's part. For MGH, they believe that community partnerships and a strong relationship between the academic and community centers focused on sharing expertise on outpatient step-up dosing can aid in addressing community provider hesitancy and increasing the level of knowledge in how to best utilize elranatamab overall and in the outpatient setting.

Commentary by E. Bridget Kim, PharmD, BCPS, BCOP: *Expanding access to care requires greater support for community sites, particularly in overcoming hesitancy around initiating step-up dosing. Partnering closely with community providers and sharing successful outpatient models can empower sites to adopt these approaches and enhance patient care.*

Conclusions and Summary

Elranatamab is an important and efficacious therapeutic advance for patients with RRMM, particularly those with limited treatment options. However, the complex dosing and AE profile require optimal patient monitoring and care when implementing into clinical practice, paving the way for continuous improvement initiatives. The QI/QA initiatives at MGH are a model example for what factors should be considered when starting to implement elranatamab into clinical practice, particularly in outpatient administration. The BOSS program, through their efforts, observed reductions in CRS rates and CRS-related complications.[21] The results from MGH's initiatives demonstrate the value of combining novel therapies with QI and QA frameworks to ensure safe care, optimize outcomes, and establish scalable models for delivering complex oncology treatments.

Future initiatives will focus on expanding workflows to other bispecific therapies, addressing health equity challenges, and ensuring long-term program sustainability through continued education, resource investment, and real-time monitoring.

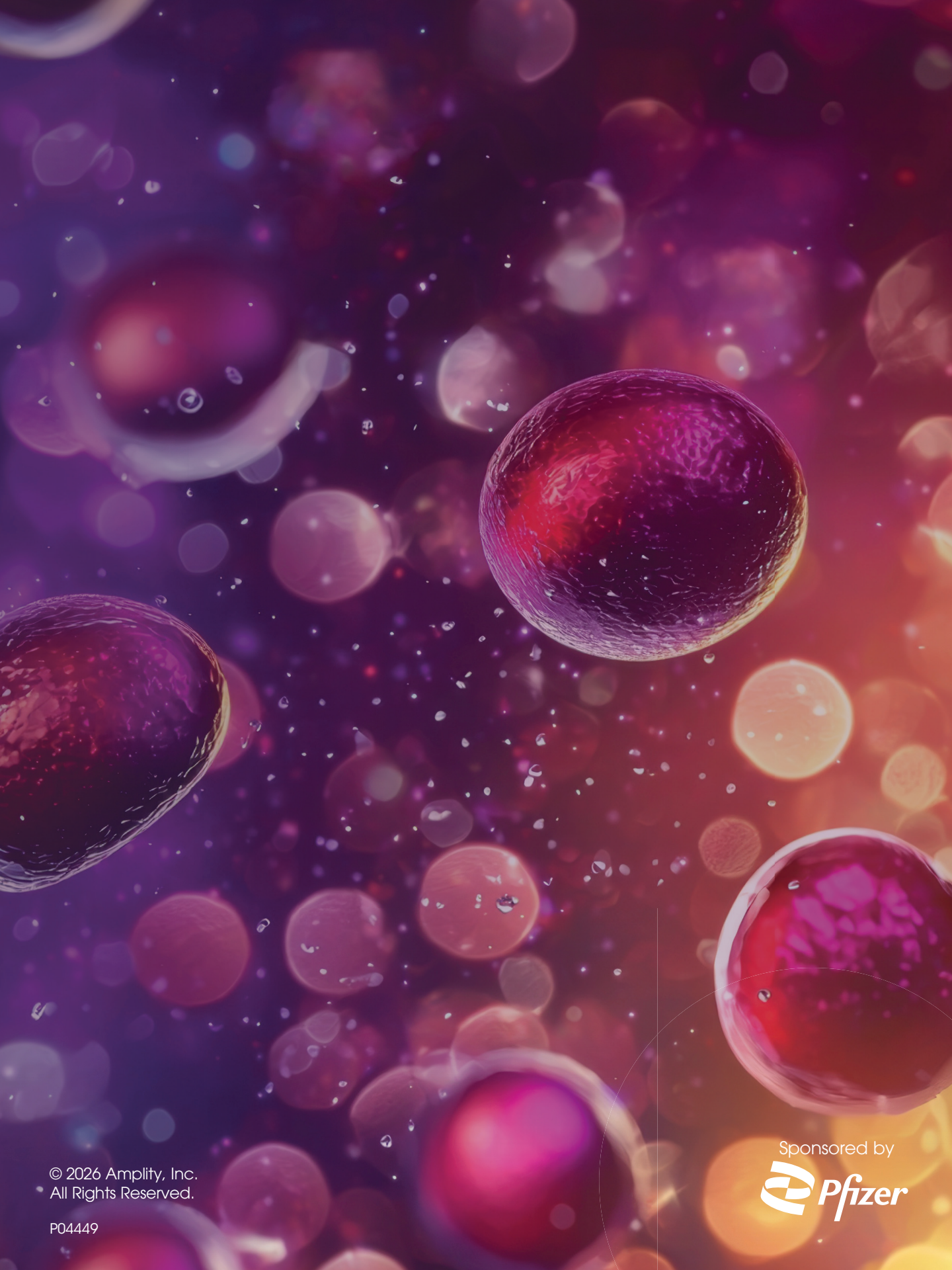
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List of Abbreviations

AE	Adverse Event
ASCT	Autologous Stem Cell Transplantation
BCMA	B-cell Maturation Antigen
BCOP	Board-Certified Oncology Pharmacist
BCPS	Board-Certified Pharmacotherapy Specialist
BOSS	Bispecific Outpatient Safe Step-Up Program
CAR	Chimeric Antigen Receptor
CD3	Cluster of Differentiation 3
CD38	Cluster of Differentiation 38
CMPP™	Certified Medical Publication Professional
CR	Complete Response
CRS	Cytokine Release Syndrome
Dex	Dexamethasone
Elra	Elranatamab
FDA	Food and Drug Administration
ICANS	Immune Effector Cell–Associated Neurotoxicity Syndrome
ID	Infectious Disease
iMiD	Immunomodulatory Drug

mAB	Monoclonal Antibody
MGH	Massachusetts General Hospital
MM	Multiple Myeloma
MRD	Measurable Residual Disease
NCCN	National Comprehensive Cancer Network
ORR	Overall Response Rate
PD	Progressive Disease
PFS	Progression-Free Survival
PI	Proteasome Inhibitor
QA	Quality Assurance
QI	Quality Improvement
QW	Every Week
Q2W	Every 2 Weeks
Q4W	Every 4 Weeks
RRMM	Relapsed/Refractory Multiple Myeloma
SC	Subcutaneous
Tal	Talquetamab
TEAE	Treatment-Emergent Adverse Event
Tec	Teclistamab



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