

# A Focus on Special Populations in Relapsed Multiple Myeloma

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Authors' disclosures of conflicts of interest are found at the end of this article.

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## Abstract

The overall care of patients with multiple myeloma can present similar challenges. However, disparities in health care require that providers consider each individual's unique circumstances. Disparities based on ethnic/racial group, religion, socioeconomic status, age, sexual orientation or gender identity, or other characteristics can lead to patients receiving less than optimal care and therefore poorer outcomes. Patients who have received more than two lines of therapy can acquire new genetic changes, accelerated cadence of relapse, and suffer from disease sequelae such as pain from prior or ongoing skeletal fractures, recurrent infections, and progressive decline in organ function. Numerous treatment options remain for patients in their first three relapses. Well-designed clinical trials with newer drugs are preferred. Clinicians should discuss clinical trial options and availability with all patients in spite of disparities that may exist. Patients facing disparities are at risk for suboptimal care and should be closely monitored and provided appropriate resources. Continued attention to disease and organ surveillance are critical throughout the course of the disease.

## CASE STUDIES

### Case Study 1: Overview and Diagnosis

Jen is a 64-year-old African American woman who is a Jehovah's Witness. Jen was diagnosed with smoldering myeloma in 2013. She had 20% monoclonal cells in her bone marrow and a serum M protein of 2.0 g/dL. There were no signs of end-organ damage. She was monitored with serum and urine studies every 3 to 4 months until 2017. Her monoclonal protein had slowly climbed to 4.1 g/dL. A bone marrow biopsy showed 80% monoclonal cells with a gain of 1q21 on FISH. She remained asymptomatic and without renal dysfunction, anemia, or bone lesions.

Regarding her religious beliefs, her care team discussed treatment approaches limiting the need for blood transfusions. After the discussion with Jen, it was clear she did not want to proceed with an autologous stem cell transplant (ASCT). At this time, she also declined clinical trial options.

Jen's treatment team suggested bortezomib, lenalidomide, and dexamethasone (VRd), but she was afraid of the side effects of lenalidomide and did not have insurance coverage at the time of diagnosis. Her initial therapy was cyclophosphamide, bortezomib, and dexamethasone (Cy-BorD). The advanced practitioner (AP) arranged a meeting with a financial counselor to seek funding support for medication copays and secure insurance to address her economic issues.

**Table 1. Laboratory Testing, Radiologic Imaging, and Myeloma Parameters at Diagnosis for Roberto**

*Labs*

- Complete blood count
  - » WBC 2.4 g/dL (range 3.5–5.0 g/dL)
  - » Hgb 9.5 g/dL (range 11–15 g/dL)
  - » Platelets  $156 \times 10^9/L$
- Chemistry panel
  - » Calcium 10.7 mg/dL (range 8.5–10.2 mg/dL)
  - » Albumin 3.5 mg/dL (range 3.5–5.0 mg/dL)
  - » Creatinine 2.5 g/dL (range 0.9–1.2 g/dL)
- Myeloma-specific labs
  - » Serum free kappa 19.4 mg/L, lambda 10.4 mg/L, kappa:lambda ratio: 1.2 (normal)
  - » Serum IgA 3900 (normal 35–320 mg/dL); IgA kappa band on serum immunofixation
  - » M-spike 2.3
  - » Serum beta-2 microglobulin 8.2
  - » Serum LDH 225

*Radiologic imaging*

- Plain film x-ray
  - » Showed T11 and T12 compression fractures. Expansile and destructive lesion is noted involving right clavicular head adjacent to right sternoclavicular joint with surrounding soft tissue swelling. Spine MRI demonstrated a chest wall mass and extensive diffuse osseous metastatic disease mainly affecting thoracic and lumbar spine. Skeletal survey lytic lesions were identified in his parietal bone.
- Bone marrow biopsy
  - » 30.9% kappa restricted plasma cells positive for CD38, CD56, CD117, CD138, and negative for CD19 and CD45. Bone marrow biopsy reveals 45% intrabecular plasma cells. Aspirate 30% plasma cells; standard risk FISH [no gain 1q, t(11;14), t(14;16) or 17p deletion].

*Staging*

- IgA kappa multiple myeloma; complicated by renal insufficiency and extensive bony disease involvement; ISS stage II and DS stage IIIA. Elevated beta-2 microglobulin, elevated creatinine, hypercalcemia, and anemia
- Intervention: Underwent T11 and T12 successful kyphoplasty for which Roberto reported immediate relief from his back pain.

*Note.* WBC = white blood cell count; Hgb = hemoglobin; LDH = lactate dehydrogenase; ISS = International Staging System; DS = Durie-Salmon.

After four cycles of CyBorD, Jen achieved only a 50% reduction in her serum paraprotein, a partial response. Her care team discussed goals of care, and the hope was for a complete response (CR), knowing that depth of response is a surrogate marker of progression-free survival (Landgren & Iskander, 2017). The AP shared with Jen that studies in newly diagnosed patients support the role of ASCT as a mechanism to deepen response, but Jen still did not want to proceed with ASCT (Vij et al., 2015). The AP discussed the risks, benefits, side effects, and alternatives to treatment. Their recommendation was carfilzomib, lenalidomide, and dexamethasone (KRd).

After a discussion on goals of care, Jen thought it was good to change treatment with a goal to deepen her response. Fortunately, she received free lenalidomide through the manufacturer's patient assistance program. The financial coordinator also guided her towards enrollment in Medicare services. She received KRd for three cycles, although she had no change in her serum markers or monoclonal protein. Her team advised a second opinion by a myeloma expert who recommended daratumumab, pomalidomide, bortezomib, and dexamethasone (DPVd). Jen received this for seven cycles, with a partial response. She continued feeling reasonably well throughout her treatment with no hospitalizations, adverse side effects, or end-organ damage. Jen was able to work and maintain her quality of life. Unfortunately, after 8 months, her paraproteins began to double, consistent with biochemical disease progression.

### Case Study 2: Overview and Diagnosis

Roberto is a 45-year-old Spanish-speaking man who was diagnosed with multiple myeloma in 2010. He emigrated to the United States as a teenager and has a history of diabetes mellitus, hypertension, obesity, and a 20-year smoking history. At the time of diagnosis, he worked more than full-time as a factory worker. He experienced increasing pain in his low back and presented to his primary care provider. His baseline disease evaluation is shown in Table 1.

Roberto could no longer work once he was diagnosed with MM. He is neither married nor

partnered and has no children. The oncology team arranged for an interpreter to be present at each visit. The oncology team suggested that Roberto participate in a clinical trial for newly diagnosed MM patients, due to his young age. In the particular phase III study the team was considering, patients were randomized to receive bortezomib with lenalidomide and dexamethasone (RVd) vs. lenalidomide and dexamethasone (Rd) alone. The AP explained that the objective of this clinical trial was to determine the best timing for ASCT in newly diagnosed myeloma patients.

Roberto was concerned about the cost of treatment and whether he could work. The study nurse was able to provide a consent form in Spanish, which at the time was not standard. He agreed to participate in the study and was

randomized to receive an upfront ASCT. He achieved a complete response to the first four cycles of RVd, and his stem cell collection and transplant went well. Three months after ASCT, he started on maintenance therapy of low-dose lenalidomide, and he remained in remission for 5 years. At a routine follow-up visit, the AP and study nurse noted the IgA level was rising, along with anemia and an increased creatinine level. He had no new symptoms and was thus diagnosed with biochemical relapse. He remained fit, and he and his team decided to change treatment. He received carfilzomib, lenalidomide, and dexamethasone (KRd) as second line. His second relapse occurred sooner than anticipated, and his third line was daratumumab, pomalidomide, and dexamethasone (DPd).

**T**he care of patients with multiple myeloma grows more challenging with relapse. In addition, disparities in health care can impact the quality of care that patients with relapsed multiple myeloma receive. These disparities exist with regard to ethnic/racial group, religion, socioeconomic status, age, sexual orientation or gender identity, and other characteristics. Advanced practitioners (APs) in oncology are in an ideal position to closely monitor and provide appropriate resources to patients, implement early supportive care, and offer clinical trials to all patients.

### CASE STUDY 1: TREATMENT

At the time of Jen's progression, a new and exciting clinical trial had just opened at her cancer center. This trial involved belantamab mafodotin-blmf (see Table 2 for approved drugs and combinations). Although initially Jen was not interested in clinical trials, her treatment team felt it was important to discuss and thoroughly review all aspects of the trial with her. Jen then decided to enroll. Through shared decision-making, she and her team agreed the efficacy data, tolerance profile, and dosing schedule of the drug was best for her. She enrolled in December 2018 and received belantamab mafodotin, a B-cell maturation antigen (BCMA) antibody-drug conjugate (ADC), for more than 2 years.

### Belantamab Mafodotin

Belantamab mafodotin is the first therapy targeted against BCMA. It is approved for patients with MM who have received at least four prior therapies, including an anti-CD38 antibody, a proteasome inhibitor, and an immunomodulatory agent. Belantamab mafodotin is an IV infusion given over 30 minutes every 3 weeks (GSK, 2020). The target, BCMA, is a protein overexpressed on myeloma cells. It is part of the tumor necrosis family (TNF). BCMA helps myeloma cells survive by increasing chemotherapy resistance and immunosuppression in the bone marrow. When the drug binds to BCMA on the surface of myeloma cells, it gets internalized and then releases monomethyl auristatin F (MMAF), a microtubule inhibitor, and interrupts critical cell processes resulting in cell arrest and apoptosis. There is also antibody-dependent cellular toxicity, immunogenic cell death, and BCMA receptor signaling inhibition (Lonial et al., 2020, 2021).

The most common side effects to be aware of are ocular toxicity and thrombocytopenia. Generally, eye symptoms related to treatment are new for myeloma patients, and it is important to keep in mind that with belantamab mafodotin, the patient's symptoms do not always correlate with the severity of the toxicity. The damage occurs on the cornea and is called keratopathy; it consists of microcyst-like epithelial changes (MECs). Keratopa-

**Table 2. Approved Drugs and Combinations**

Drug	2nd line	3rd line	≥ 4th line	Approved combinations
Bortezomib	✓	✓	✓	VMP, VTD, D-VTd, D-VMP
Lenalidomide	✓	✓	✓	VRd, Rd, DRd, KRd, IRd
Carfilzomib	✓	✓	✓	KRd, Kd, DKd, Isa-Kd
Pomalidomide	✓	✓	✓	Pd, DPd, EPd, PCd, Isa-Pd
Daratumumab		✓	✓	DRd, DVd, DPd, D-VMP, DKd
Ixazomib	✓	✓	✓	IRd
Elotuzumab	✓	✓	✓	ERd, EPd
Selinexor	✓	✓	✓	Selinexor-Vd, Selinexor-dex
Isatuximab	✓	✓	✓	Isa-Pd, Isa-Kd
Belantamab mafadotin		✓	✓	
Idecabtagene vicleucel			✓	
Ciltacabtagene autoleucel			✓	

*Note.* VMP = bortezomib, melphalan, and prednisone; VTD = bortezomib, thalidomide, and dexamethasone; D-VTd = daratumumab, bortezomib, thalidomide, and dexamethasone; D-VMP = daratumumab, bortezomib, melphalan, and prednisone; VRd = bortezomib, lenalidomide, and dexamethasone; Rd = lenalidomide and dexamethasone; DRd = daratumumab, lenalidomide, and dexamethasone; KRd = carfilzomib, lenalidomide, and dexamethasone; IRd = ixazomib, lenalidomide, and dexamethasone; Kd = carfilzomib and dexamethasone; DKd = daratumumab, carfilzomib, and dexamethasone; Isa-Kd = isatuximab, carfilzomib, and dexamethasone; Pd = pomalidomide and dexamethasone; DPd = daratumumab, pomalidomide, and dexamethasone; EPd = elotuzumab, pomalidomide, and dexamethasone; PCd = pomalidomide, cyclophosphamide, dexamethasone; Isa-Pd = isatuximab, pomalidomide, and dexamethasone; DRd = daratumumab, lenalidomide, and dexamethasone; DVd = daratumumab, bortezomib and dexamethasone; DPd = daratumumab, pomalidomide, and dexamethasone; ERd = elotuzumab, lenalidomide, and dexamethasone.

thy seems to be related to the MMAF as reported in other MMAF ADCs (Farooq et al., 2020). Due to this toxicity, there is a Risk Evaluation and Mitigation Strategies (REMS) program for the drug. Every patient needs to have an eye exam before starting belantamab and before each dose. Exams consist of visual acuity and slit-lamp microscopy, which an optometrist or ophthalmologist can perform. The eye care specialist provides a grading of the patient's vision and any changes to their cornea. The median time to eye toxicity onset is approximately 2 months; if the patient experiences a grade two or greater change, the drug should be held until improvement. Dose interruptions and dose reductions occur in most patients, although responses are maintained in those responding to treatment, despite dose interruptions (Lonial et al., 2020, 2021).

Jen received five cycles of belantamab before developing a grade 2 keratopathy. She described

blurry vision when reading at night. There was no pain, and she was hesitant to hold treatment because otherwise, she felt very well and had been responding nicely. Her cycle six was delayed 3 weeks, and she continued to use preservative-free artificial tears. By the next scheduled dose, her corneal findings had improved to grade 1. She continued with stable eye exams for a couple more doses, then held at cycle eight for another grade 2 event. About a year into treatment, she had a grade 3 event during which she had pain in both eyes by the end of the day. She also had vision changes, and with the grade 3 severity, her subsequent doses were given at a reduced 1.9 mg/kg (Table 3). Overall, she had a partial response that lasted over 2 years. She was able to work and did not suffer from side effects that kept her at home.

In January 2021, Jen progressed while on belantamab mafodotin with a subsequent increase in serum paraprotein (Table 4). Based on her positive

**Table 3. Belantamab Mafodotin: Ocular Toxicity and Intervention**

Treatment cycle	Intervention/ Toxicity grade	Dates drug held, dose adjustment	Outcome	Disease status
Cycle 6	Dose held for grade 2 ocular toxicity	No treatment from March 14, 2019	Treatment restarted April 22, 2019, with improved vision	Stable disease
Cycle 8	Dose held for grade 2 ocular toxicity	No treatment from May 13, 2019	Treatment restarted May 24, 2019, with improved vision	Stable disease
Cycle 25	Dose reduced for grade 3 keratopathy	Reduced from 2.4 mg/kg to 1.9 mg/kg when vision improved to grade 1	Treatment restarted with improved vision	Stable disease until eventual progressive disease

experience with clinical trials, she was interested in finding another novel drug to treat her MM.

### Discussion

Understanding side effects and management strategies, including the REMS program, is critical for APs. The purpose of a REMS program is patient safety. The program for belantamab ensures close monitoring of ocular toxicity and collaboration of pharmacists, nurses, and APs so that patients receive the appropriate dosing of belantamab. For APs, it involves counseling patients and ensuring the correct documentation is verified before treatment. Similar to other REMS, the drug company needs verification of the prescribing provider's approval of treatment, including the dose.

This case study contains several key points, which are quite common when treating multiple myeloma. Treatment-related goals need to consider patients' religious, ethnic, and financial concerns. Jen's religion played a vital role, as she could not receive blood transfusions, limiting some treatment options due to severe anemia. Her first treatment line was effective, although

response rates were lower than with the alternative at the time (bortezomib, lenalidomide, and dexamethasone, or VRd; Chakraborty et al., 2016). In 2017, at the time of her diagnosis, data to support using KRd or daratumumab-containing induction regimens were only available in the context of a clinical trial. Another important part of the treatment decision was that Jen did not have insurance, and so financial barriers directed decisions. CyBorD can all be given parenterally in an infusion center while coverage and financial support are pursued.

Although initially, Jen did not want to participate in a clinical trial, the AP and treatment team spent time reviewing the risks and benefits. She would have access to a therapy that is not yet approved and the whole clinical team for support and monitoring. Studies have shown racial and ethnic disparities in participation in MM clinical trials (Ailawadhi et al., 2018; Guerra et al., 2021; Pierre & Williams, 2020). Common barriers can be overcome when a care team provides access to patients, openly discusses all options, and revisits the discussion at each treatment decision.

**Table 4. Myeloma Disease Markers While on Trial With Belantamab Mafodotin**

Date	DREAMM2 cycle	Serum lambda free LC (mg/L)	Serum M-spike (g/dL)	Urinary paraprotein (mg/dL)	Bone marrow (%)	Response (IMWG)
12/21/2018	Pre-study staging	737.0	2.18	44.2	30-40	N/A
01/11/2019	Cycle 1	155.0	2.37	-	-	N/A
12/11/2019	Cycle 14	9.9	1.01	IFE positive	< 5	Best response
09/08/2020	Cycle 23	10.68	1.44	IFE positive	< 5	Stable disease
01/03/2021	Cycle 27	101.2	2.23	IFE positive	20	Progressive disease

Note. LC = light chain; IMWG = International Myeloma Working Group.

## CASE STUDY 2: TREATMENT

After Roberto's relapse on daratumumab, he was considered triple-class refractory, and his team considered him an excellent candidate to participate in a clinical trial. Selinexor, bortezomib, and dexamethasone, were available through the BOSTON trial. Again, with the help of an interpreter and a consent form in Spanish, Roberto understood the risks, benefits, and alternatives to treatment.

Discussing treatment options with his AP, interpreter, and a friend, Roberto shared two main concerns about this clinical trial. First, he did not have a car, and it would take three buses to get to the cancer center. Second, he was worried about remembering when to take his medications and the date and time of office visits. To address his transportation difficulties, the study nurse enrolled him in a rideshare program so he would be able to request a driver to and from each visit. To address his concern about when to take his medications and request transportation, calendars, medication diary cards, and electronic reminders were offered to help him stay on schedule. All written communication was provided to Roberto in his native language of Spanish. The study nurse worked with Roberto to create calendars to follow every month.

Selinexor was given days 1, 8, 15, 22, and 29 of each 35-day cycle; bortezomib subcutaneously days 1, 8, 15, and 22 of each 35-day cycle; and dexamethasone on days 1, 2, 8, 9, 15, 16, 22, and 23 of each 35-day cycle. Prior to the first day of selinexor, the AP arranged for the patient to receive antiemetic medications and IV hydration. As part of supportive care measures, there was monitoring of his weight, gastrointestinal tolerance (nausea, vomiting, and diarrhea), cytopenias, kidney function, and administration of IV hydration. He began antinausea medications one day prior with a 5-HT<sub>3</sub> receptor antagonist, ondansetron, and dexamethasone to prevent chemotherapy-induced vomiting. The AP and oncology team assured the patient that usually, after the first month of therapy, nausea and vomiting improve.

Selinexor is a selective inhibitor of nuclear export (SINE) that blocks XPO1, which is overexpressed in myeloma. Selinexor reversibly binds to the nuclear export system causing nuclear

protein buildup and stimulation of tumor suppressor proteins, which then causes tumor cell apoptosis in malignant hematologic cells. Exportin 1 (XPO1) is the major nuclear export protein for tumor suppressor genes and other proteins. High levels of XPO1 enable cancer cells to escape tumor suppressor protein-mediated cell cycle arrest and apoptosis, or programmed cell death. Selinexor inhibits XPO1 by blocking tumor suppressor proteins from being exported from the cell's nucleus. Selinexor was first approved in combination with dexamethasone based on the results of the STORM study, where efficacy was observed in penta-refractory patients. In December 2020, the combination of selinexor with bortezomib and dexamethasone was approved by the US Food and Drug Administration for use in patients with MM who had received at least one prior therapy (Karyopharm Therapeutics, 2021; Lentzsch et al., 2021).

### Supportive Care

The most common adverse events seen in the STORM study with selinexor and dexamethasone were thrombocytopenia (73%), fatigue (73%), nausea (72%), vomiting (37%), and anemia (67%). In the phase III BOSTON study, grade 3 to 4 thrombocytopenia, anemia, and fatigue were the most common adverse events. Interestingly, gastrointestinal toxicities were lower with reduced doses of selinexor than in the STORM study. Also, the incidence of peripheral neuropathy was lower in patients who received selinexor, bortezomib, and dexamethasone (21% patients) than with bortezomib and dexamethasone (34% patients). Due to significant nausea and vomiting observed in the STORM study, 5-HT<sub>3</sub> receptor antagonist antiemetics and olanzapine can be recommended at least 1 to 2 days prior to initiation of selinexor, bortezomib, and dexamethasone therapy. All patients should be premedicated with antiemetics and other supportive care medications such as olanzapine at bedtime (Mikhael et al., 2020).

Roberto was monitored with blood counts and body weight prior to selinexor and throughout treatment. The AP was concerned about adherence; therefore, Roberto was added to their schedule to be seen in clinic once weekly for 3 weeks.

The goal of weekly visits during bortezomib treatment was to review how Roberto was taking the selinexor, ensure that he was eating and drinking appropriate amounts of food, and if not, intravenous hydration with normal saline could be added. After the first week, Roberto reported nausea without emesis for 24 hours after selinexor, but admitted he forgot to take oral ondansetron and dexamethasone prior to selinexor. The AP wrote out instructions to take dexamethasone and ondansetron once weekly with breakfast, then take selinexor. The AP gave Roberto the opportunity to bring selinexor to the infusion area and have the treatment nurse administer oral ondansetron and dexamethasone, but he declined. Given his nausea with the first dose, the AP wrote instructions on how and when to take selinexor and translated it into Spanish, underscoring that ondansetron could be taken every 8 hours as needed for the first 48 hours after selinexor. He did not want to take olanzapine as he already takes “so many pills,” but the AP and Roberto were both optimistic this attention to how he takes the medication would prevent nausea. With this written information, Roberto’s nausea was controlled, and he was able to report a successful first month on therapy at the next scheduled office visit.

### Discussion

Several key points are included in Roberto’s case study. First, arrangements were made for an interpreter, and consent forms were translated into his language. In addition, after years of living with MM, he was unable to work and lacked transportation, a barrier to participation in clinical trials (Pierre & Williams, 2021). Finally, the AP wrote detailed information in his native language and provided close monitoring. With current electronic software on his smart phone, he can easily translate and type questions or concerns while in the office. By addressing these barriers, Roberto’s care was optimized, and he received novel medications to treat and support him effectively.

### CONCLUSION

Multiple myeloma patients with relapsed disease can encounter challenges as they face fewer treatment options. Despite differences in race, socioeconomic status, religion, or other factors,

all patients should have equal access to newer therapies such as belantamab, selinexor, and others. Addressing disparities in care and providing enhanced and early supportive care measures can help patients decrease known side effects with early intervention of antiemetics and medication management strategies. ●

### Disclosure

Dr. Steinbach has served on speakers bureaus for GSK and Karyopharm. Ms. Colson has served as a consultant for Bristol Myers Squibb, Oncopeptides, and Sanofi. Dr. Faiman has served as a consultant for Bristol Myers Squibb, GSK, Janssen, Karyopharm, Legend Biotech, Oncopeptides, Sanofi, and Takeda.

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