Beyond the Guidelines: Clinical Investigator Perspectives on the Management of Bladder Cancer

Clinical Investigator Survey

RTP
RESEARCH
TO PRACTICE

Bladder Cancer Survey Respondents

Neeraj Agarwal, MD

Andrea B Apolo, MD

Joaquim Bellmunt, MD, PhD

Anthony V D'Amico, MD, PhD

Robert Dreicer, MD, MS

Leonard G Gomella, MD

Petros Grivas, MD, PhD

Ashish M Kamat, MD, MBBS

Peter H O'Donnell, MD

Sumanta Kumar Pal, MD

Daniel P Petrylak, MD

Thomas Powles, MBBS, MRCP, MD

Jonathan E Rosenberg, MD

Fred Saad, MD

A Oliver Sartor, MD

Susan F Slovin, MD, PhD

Matthew R Smith, MD, PhD

Guru Sonpavde, MD

Robert Svatek, MD

Evan Y Yu, MD

RTP
RESEARCH
TO PRACTICE

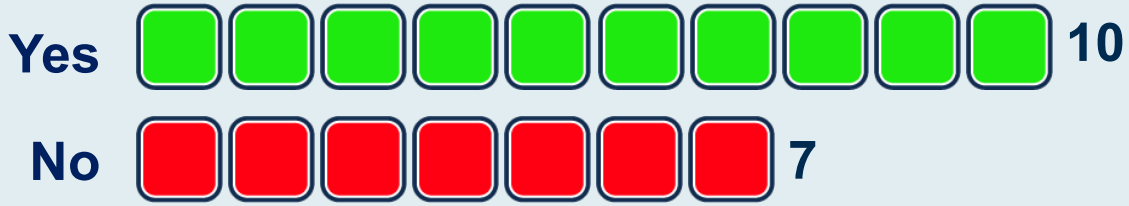
MODULE 1: Integrating Novel Agents into the Treatment Paradigm for Nonmetastatic Urothelial Bladder Cancer (UBC) — Dr Pal

RTP
RESEARCH
TO PRACTICE

In general, would you recommend pembrolizumab to a patient with BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC) who is…

65 years old, otherwise healthy and prefers not to undergo cystectomy

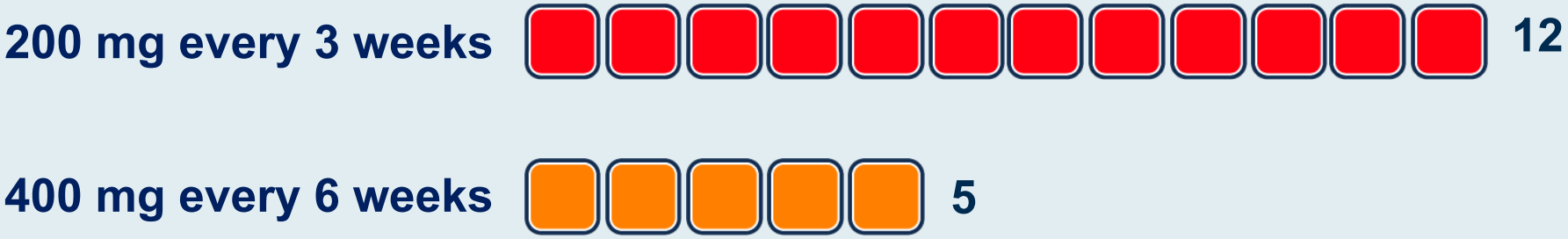
70 years old, with minor comorbidities



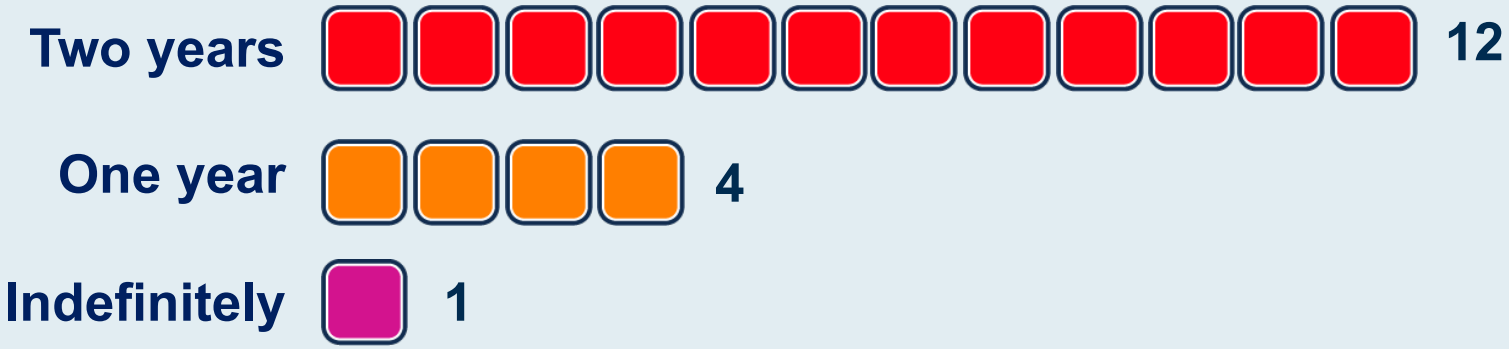
80 years old, with significant comorbidities and not a candidate for cystectomy

Survey of genitourinary cancer clinical investigators

For patients with BCG-unresponsive NMIBC to whom you opt to administer pembrolizumab, what dose and schedule do you typically use?

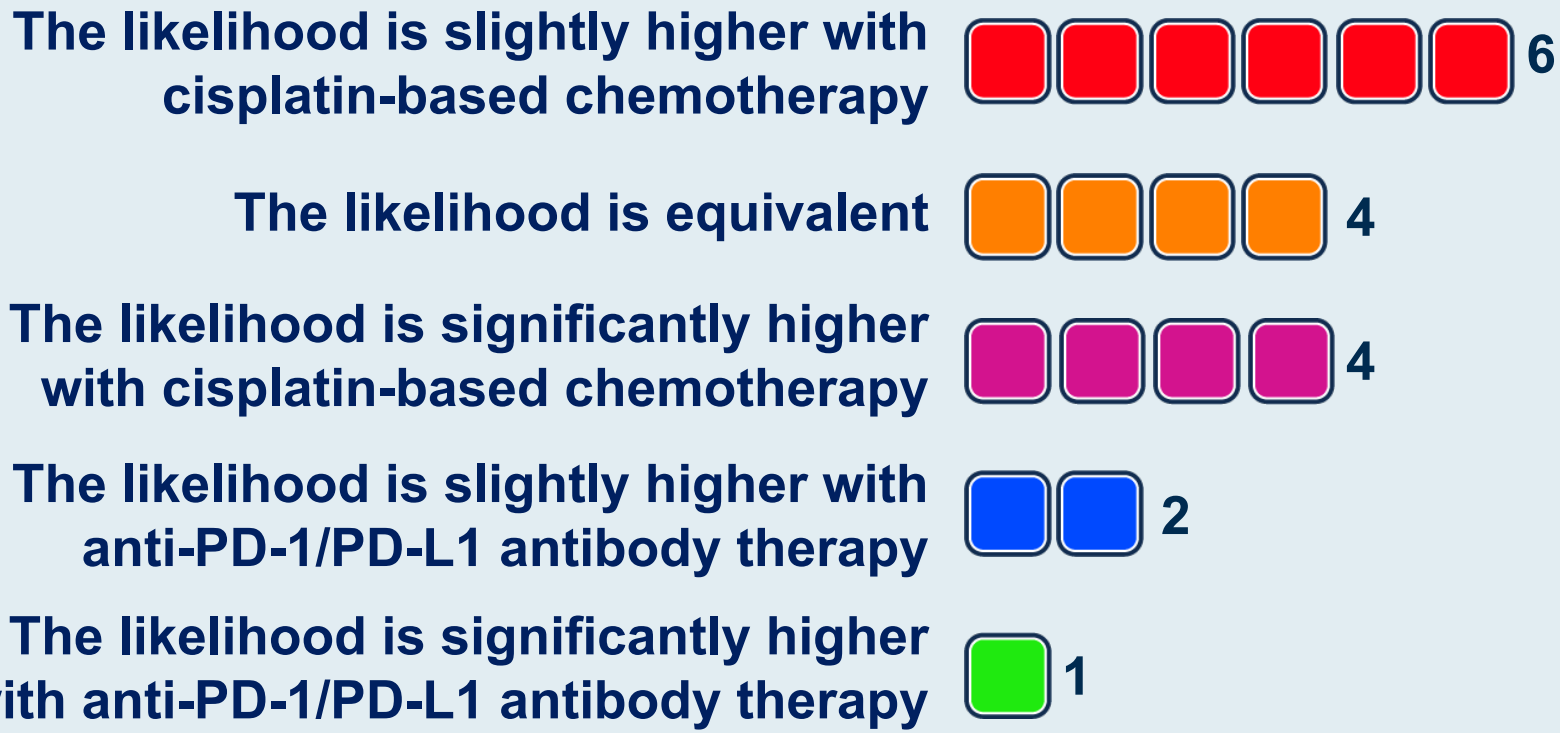


For patients with BCG-unresponsive NMIBC to whom you opt to administer pembrolizumab, what is your typical planned duration of treatment, assuming no unacceptable toxicity or disease progression?



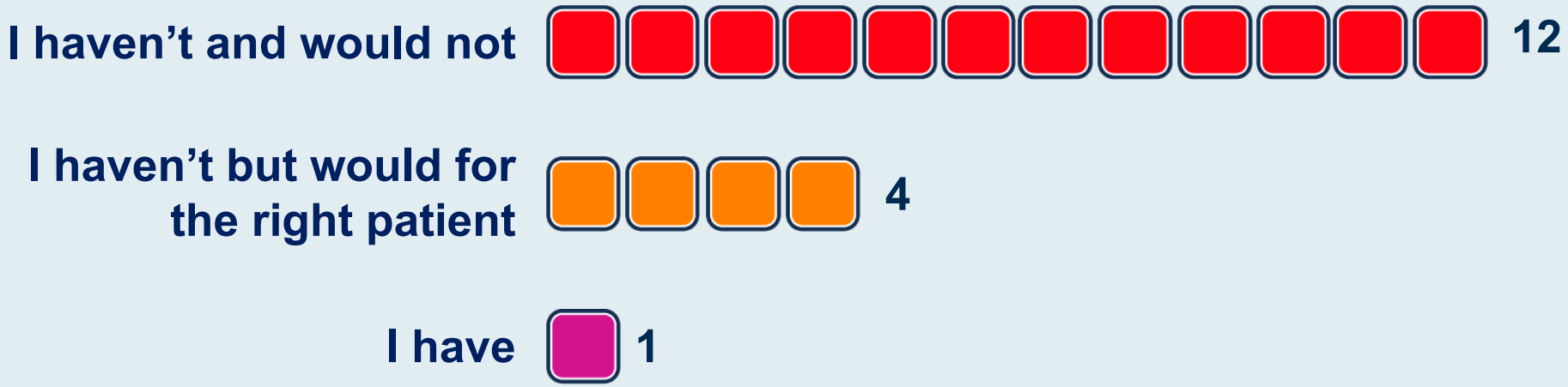
Survey of genitourinary cancer clinical investigators

Based on current clinical trial data and your personal experience, how would you compare the likelihood that a patient with muscle-invasive bladder cancer (MIBC) will achieve a pathologic complete response with neoadjuvant anti-PD-1/PD-L1 antibody therapy versus cisplatin-based chemotherapy?



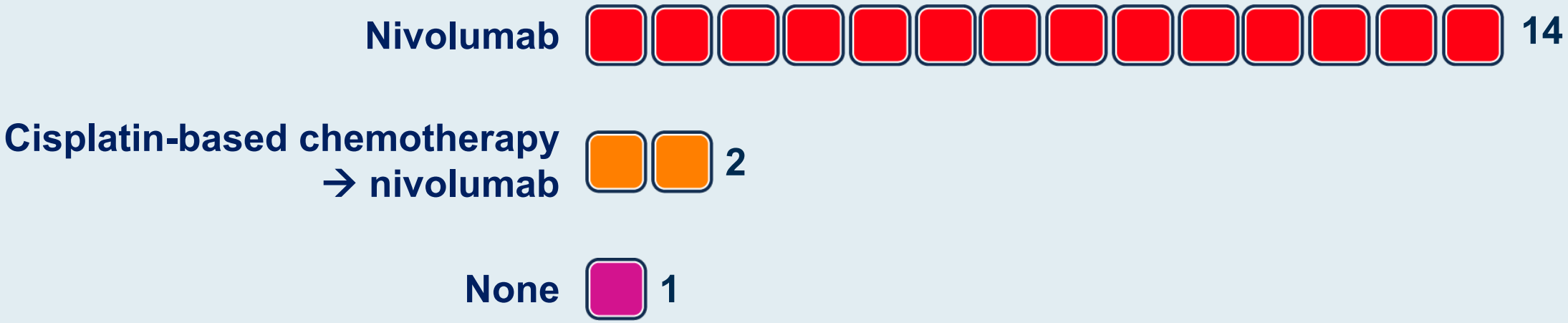
Survey of genitourinary cancer clinical investigators

Have you administered or would you administer an anti-PD-1/PD-L1 antibody as a component of neoadjuvant therapy to a patient with MIBC outside of a protocol setting?



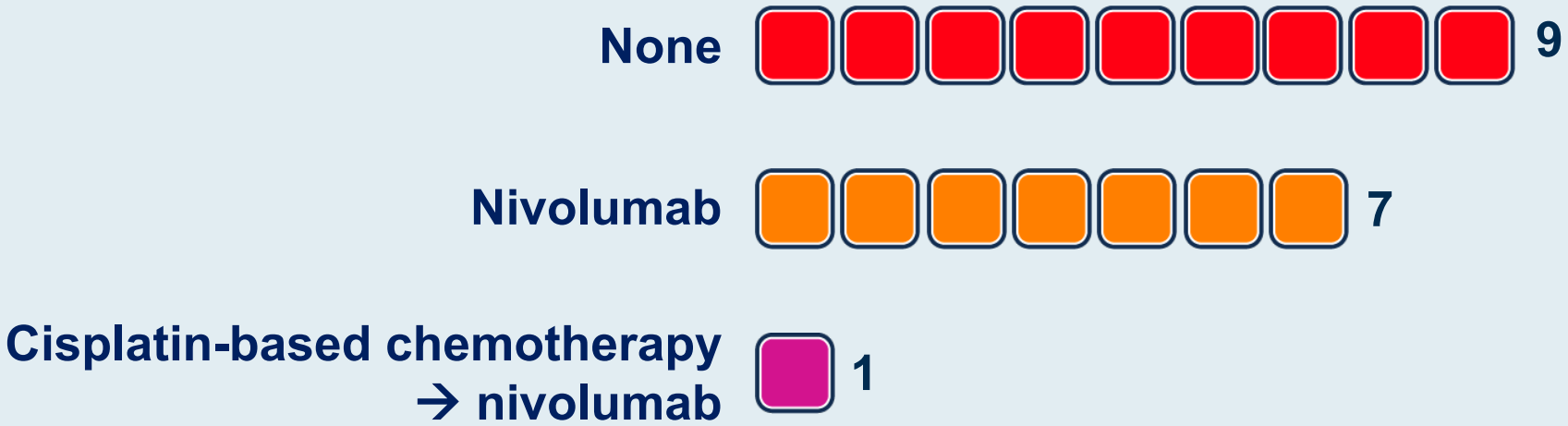
Survey of genitourinary cancer clinical investigators

A 65-year-old man receives neoadjuvant dose-dense MVAC for PD-L1-positive MIBC and undergoes cystectomy, which reveals significant residual disease and a positive pelvic lymph node. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



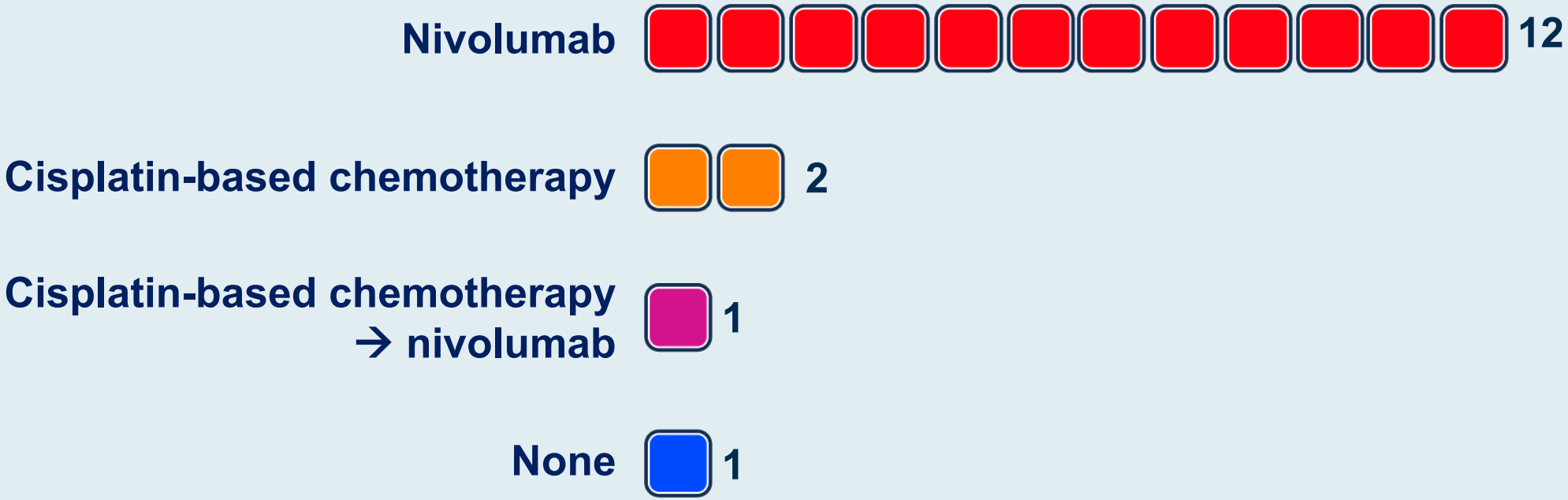
Survey of genitourinary cancer clinical investigators

A 65-year-old man receives neoadjuvant dose-dense MVAC for PD-L1-positive MIBC and undergoes cystectomy, which reveals small amounts of residual disease and negative pelvic lymph nodes. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



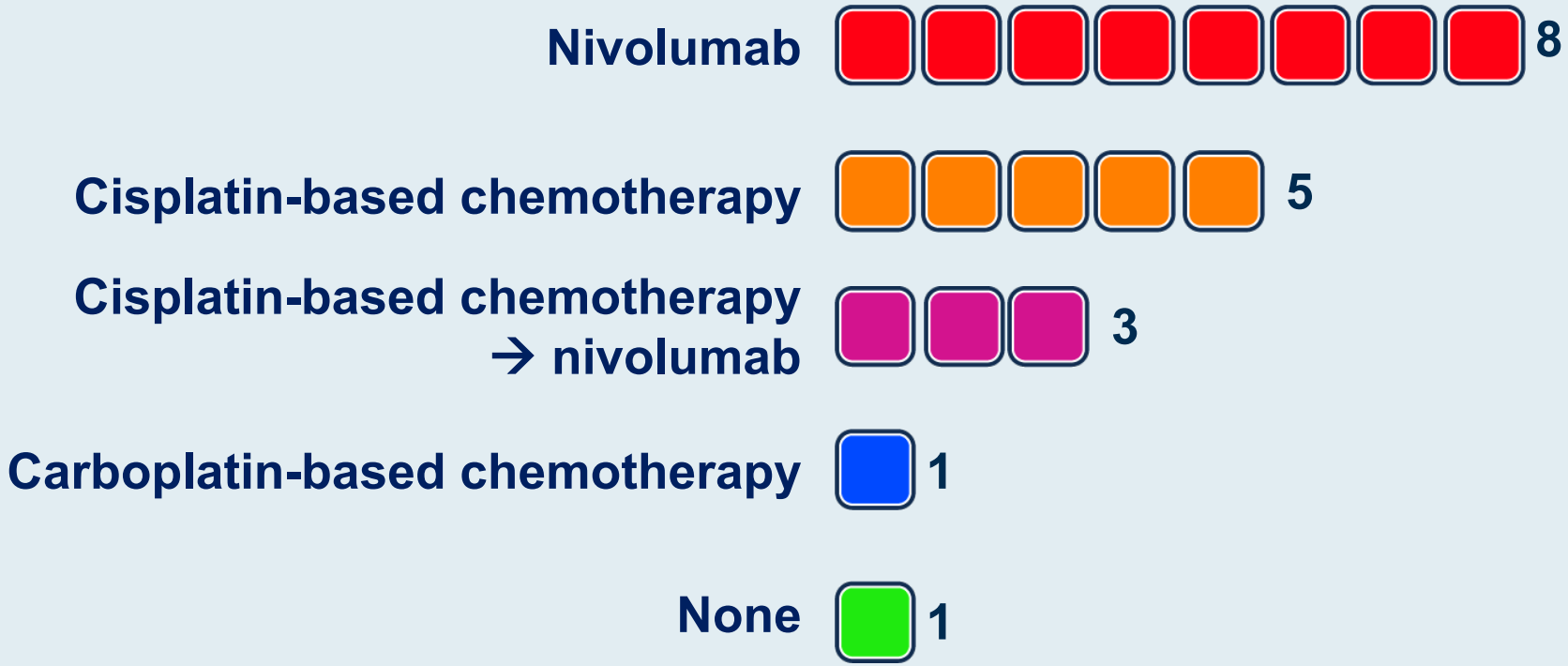
Survey of genitourinary cancer clinical investigators

A 65-year-old man receives neoadjuvant dose-dense MVAC for PD-L1-negative MIBC and undergoes cystectomy, which reveals significant residual disease and a positive pelvic lymph node. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



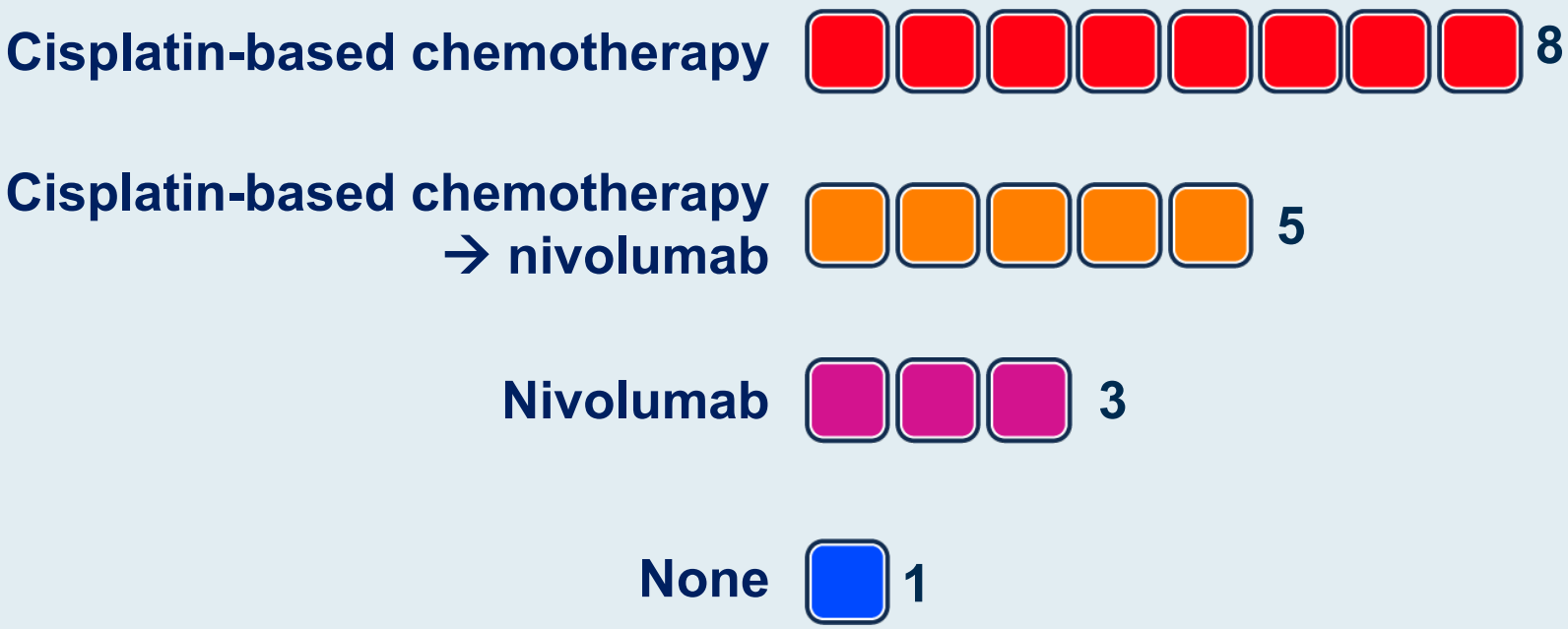
Survey of genitourinary cancer clinical investigators

A 65-year-old man receives neoadjuvant platinum-based chemotherapy for PD-L1-positive high-grade urothelial carcinoma of the ureter and undergoes nephroureterectomy, which reveals significant residual disease and a positive pelvic lymph node. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



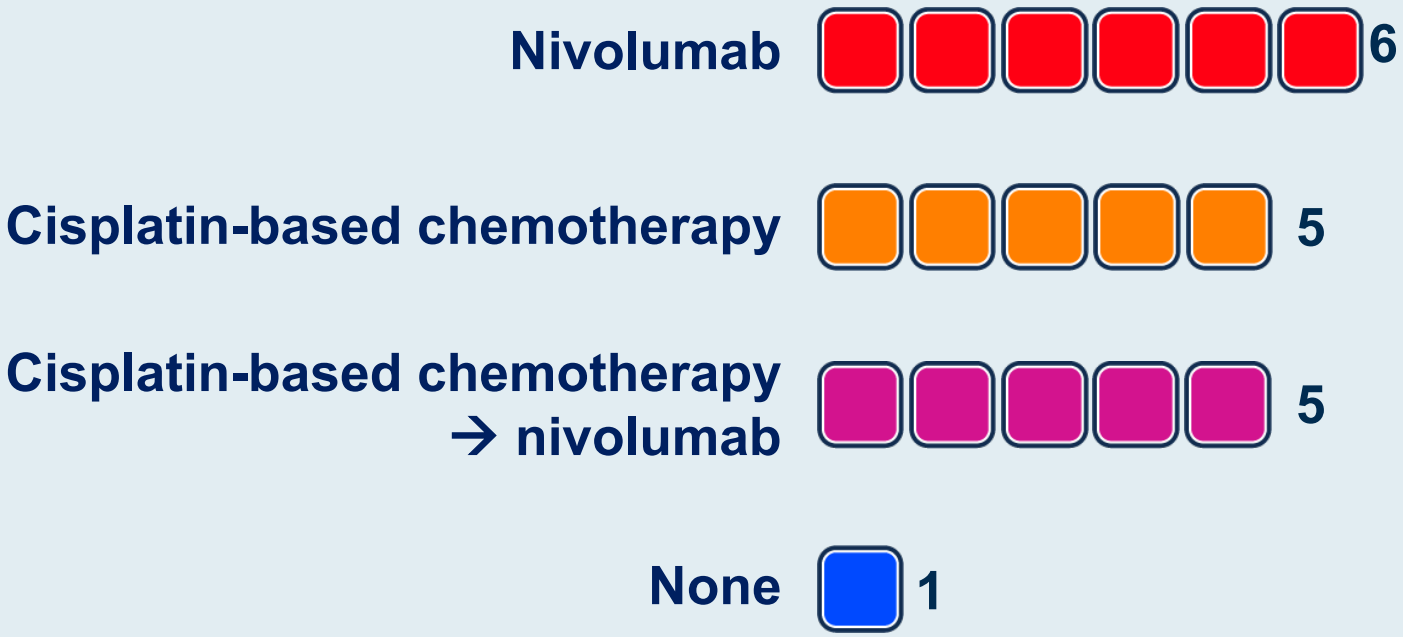
Survey of genitourinary cancer clinical investigators

A 65-year-old man is diagnosed with MIBC and undergoes cystectomy, which reveals pT3N1 PD-L1-negative disease. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



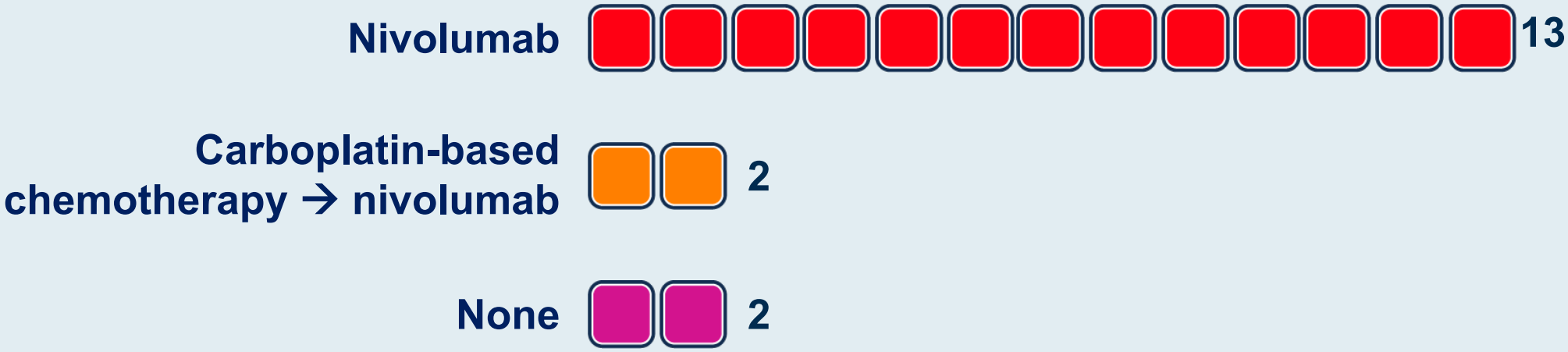
Survey of genitourinary cancer clinical investigators

A 65-year-old man is diagnosed with MIBC and undergoes cystectomy, which reveals pT3N1 PD-L1-positive disease. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?



Survey of genitourinary cancer clinical investigators

An 80-year-old man with a creatinine clearance of 45 mL/min is diagnosed with MIBC and undergoes cystectomy, which reveals pT3N1 PD-L1-positive disease. Regulatory and reimbursement issues aside, what adjuvant systemic therapy, if any, would you recommend?

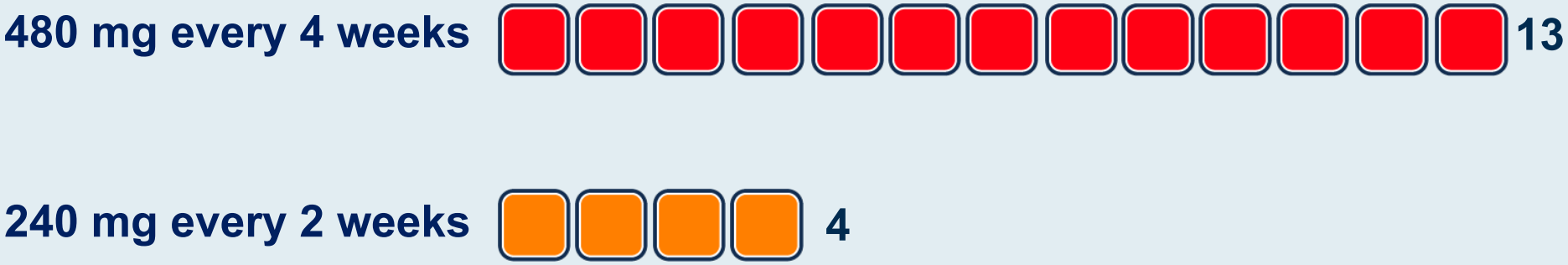


Survey of genitourinary cancer clinical investigators

Would you offer adjuvant nivolumab after radical resection to a patient with high-risk MIBC whose tumor was PD-L1-negative but had high tumor mutational burden?

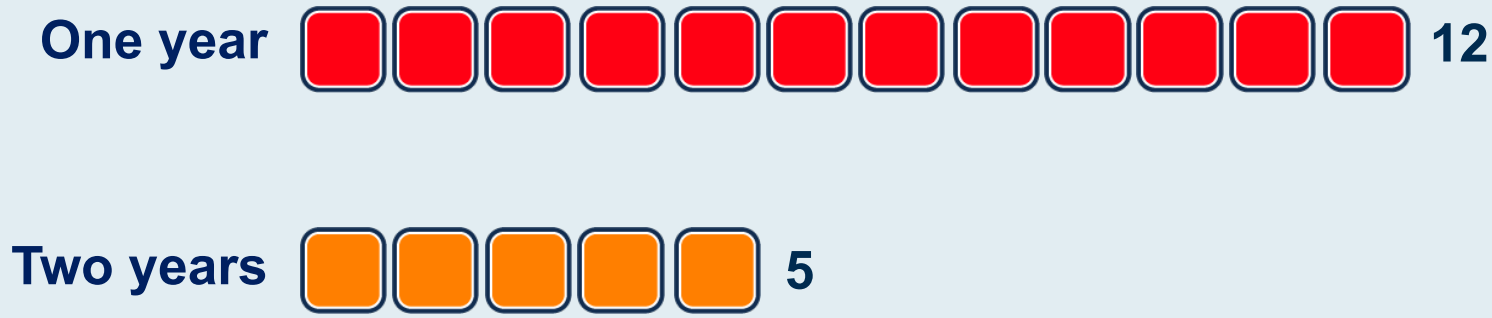
Survey of genitourinary cancer clinical investigators

For patients with high-risk MIBC for whom you opt to administer adjuvant nivolumab after radical resection, what dose and schedule do you typically use?



Survey of genitourinary cancer clinical investigators

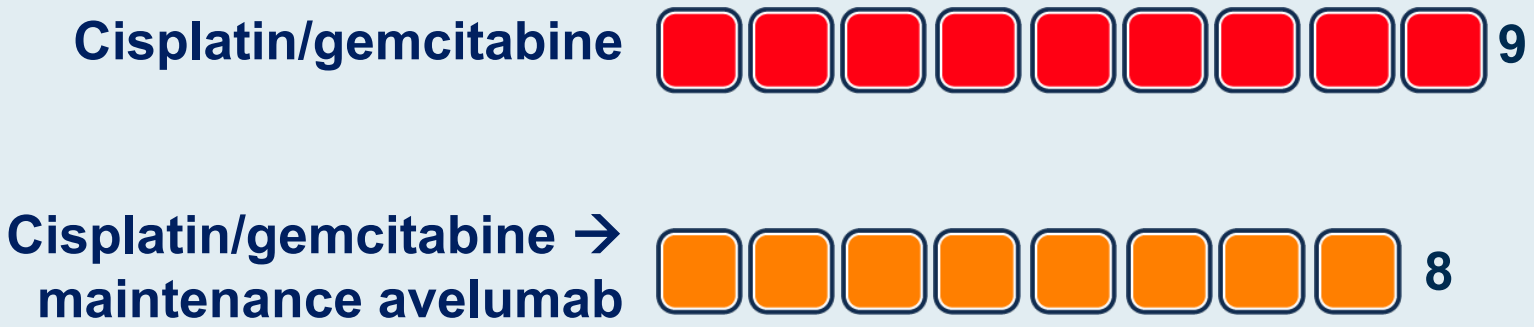
For patients with high-risk MIBC for whom you opt to administer adjuvant nivolumab after radical resection, what is your typical planned duration of treatment, assuming no unacceptable toxicity or disease progression?



Survey of genitourinary cancer clinical investigators

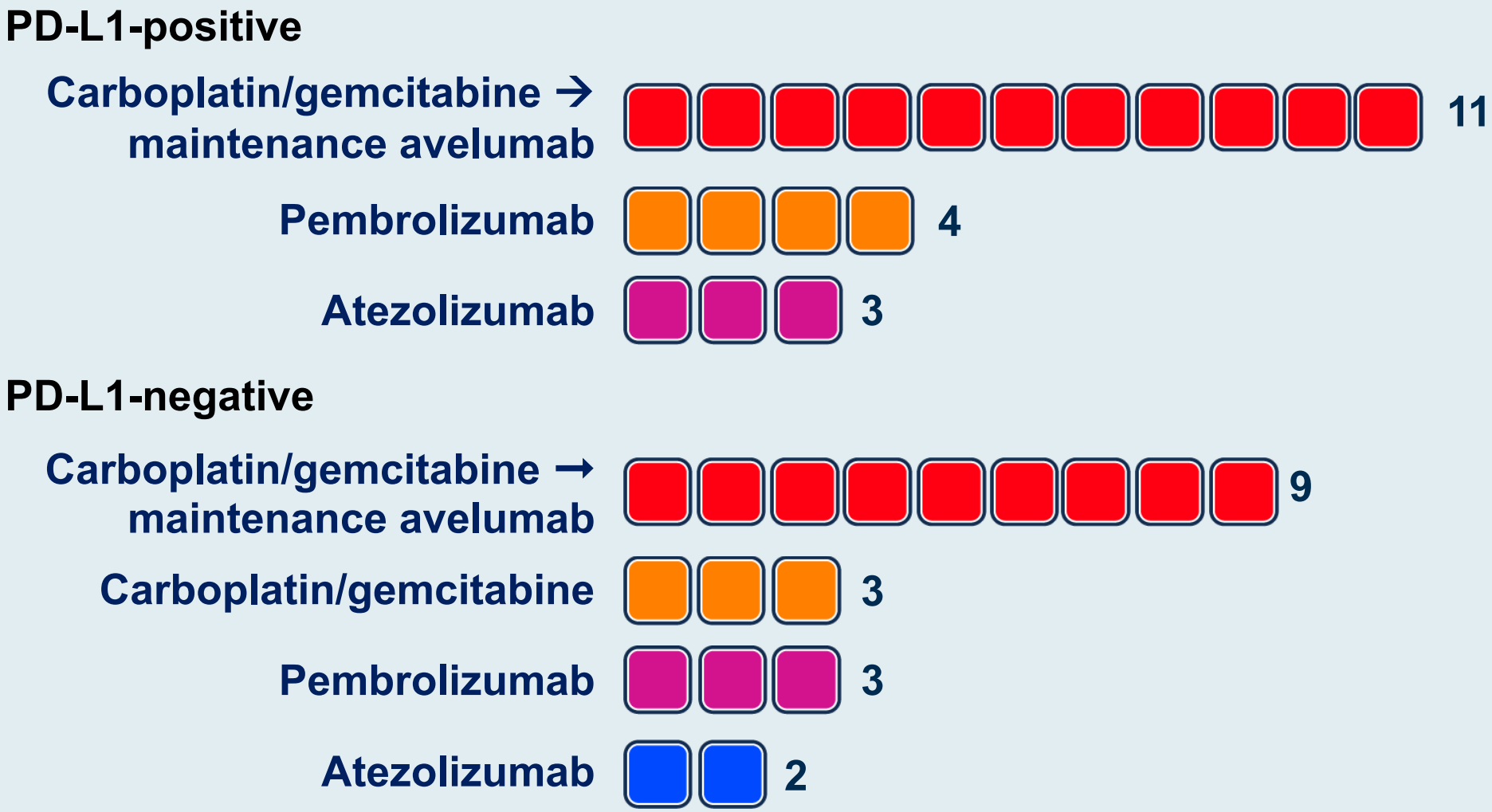
MODULE 2: Current and Future Front-Line Management of Metastatic UBC (mUBC) — Dr Gupta

What would be your preferred first-line treatment regimen for a 65-year-old patient with de novo metastatic urothelial bladder cancer (UBC)?



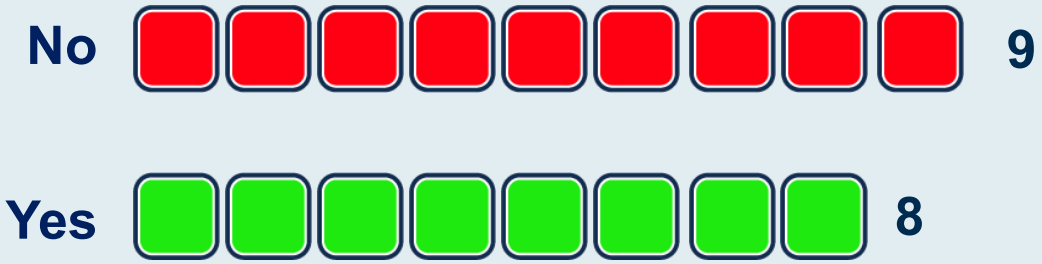
Survey of genitourinary cancer clinical investigators

What would be your preferred first-line treatment regimen for an 80-year-old patient with de novo metastatic UBC who is not a candidate for cisplatin-based chemotherapy?



Survey of genitourinary cancer clinical investigators

Are there any situations in which you are not offering avelumab maintenance to patients with metastatic UBC whose disease has not progressed after first-line platinum-based chemotherapy?



- Active autoimmune disease
- Active life-threatening autoimmune disorder
- Many patients want a break from any treatment after completion of platinum and just refuse it
- CR following cisplatin-based chemotherapy with node-only disease
- Severe autoimmune disease
- Autoimmune diseases
- Toxicity risk

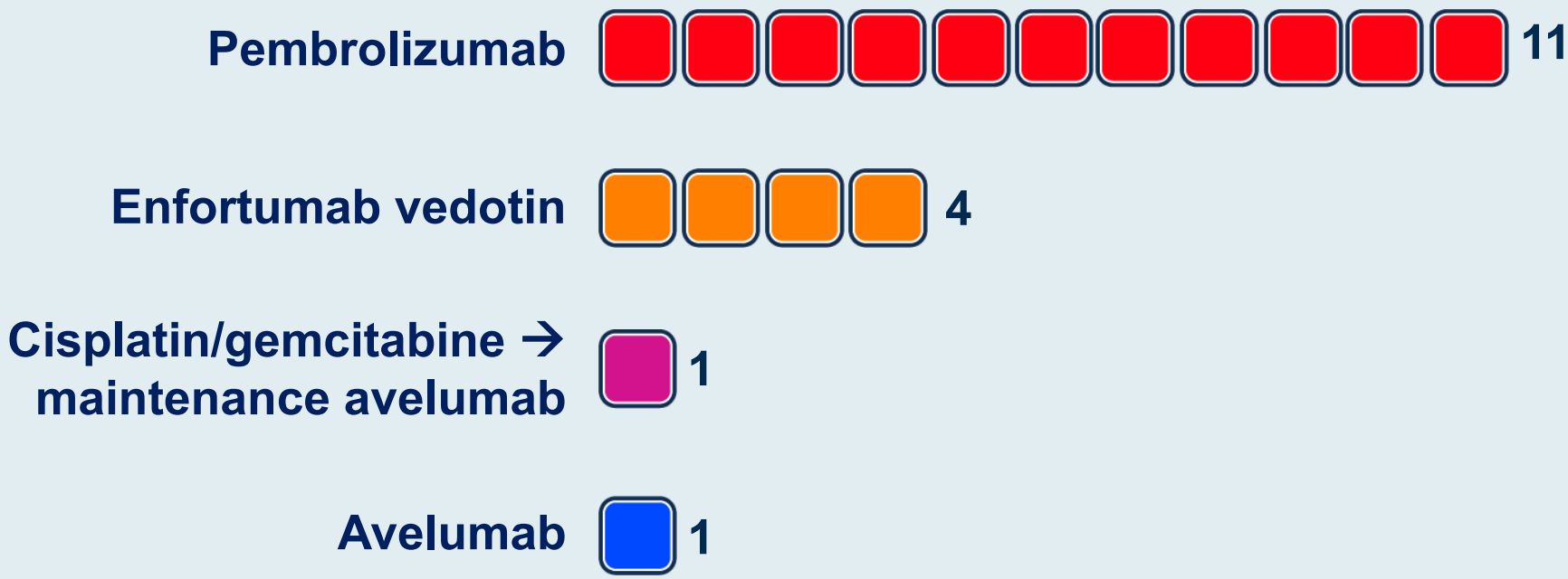
Survey of genitourinary cancer clinical investigators

For a patient with metastatic UBC whose disease has not progressed after first-line platinum-based chemotherapy, would you consider maintenance therapy with an anti-PD-1/PD-L1 antibody other than avelumab under any circumstances?

- Pembrolizumab if the patient is having issues with avelumab infusion reactions
- Over time would consider changing avelumab to pembro or nivo for patient convenience
- Insurance or schedule issues
- Pembrolizumab q 6 weeks if lives a distance from center

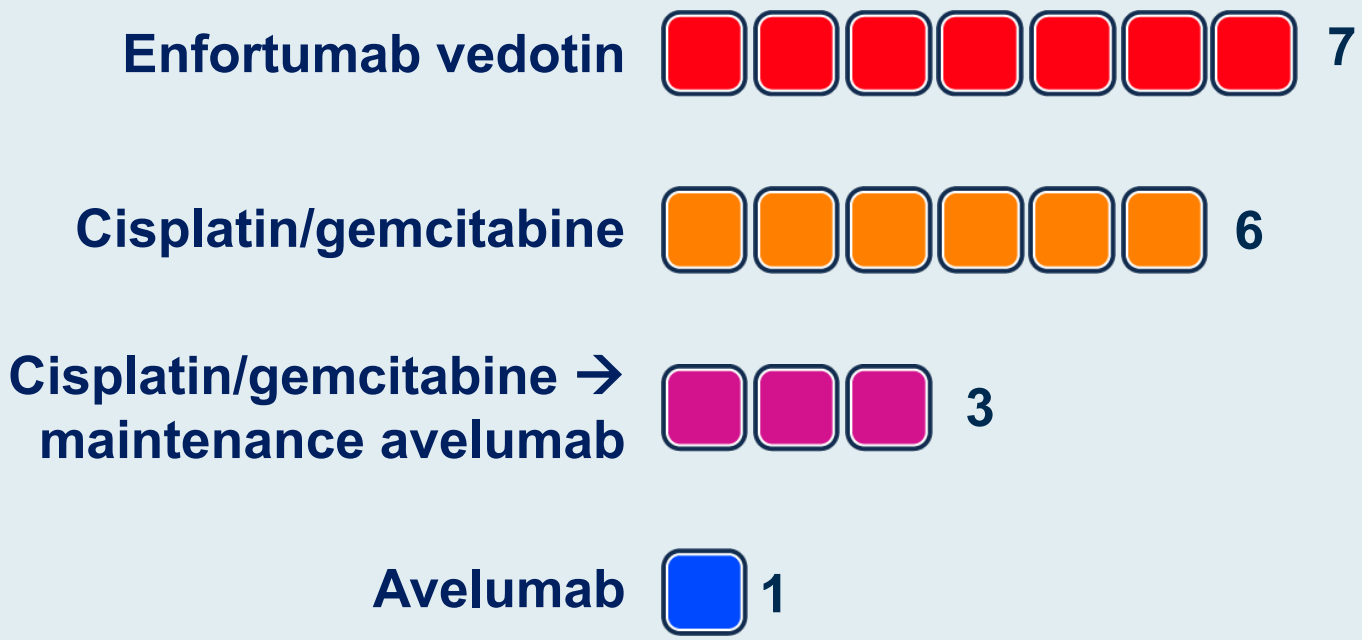
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 9 months after cystectomy and adjuvant gemcitabine/cisplatin for muscle-invasive FGFR wild-type UBC?



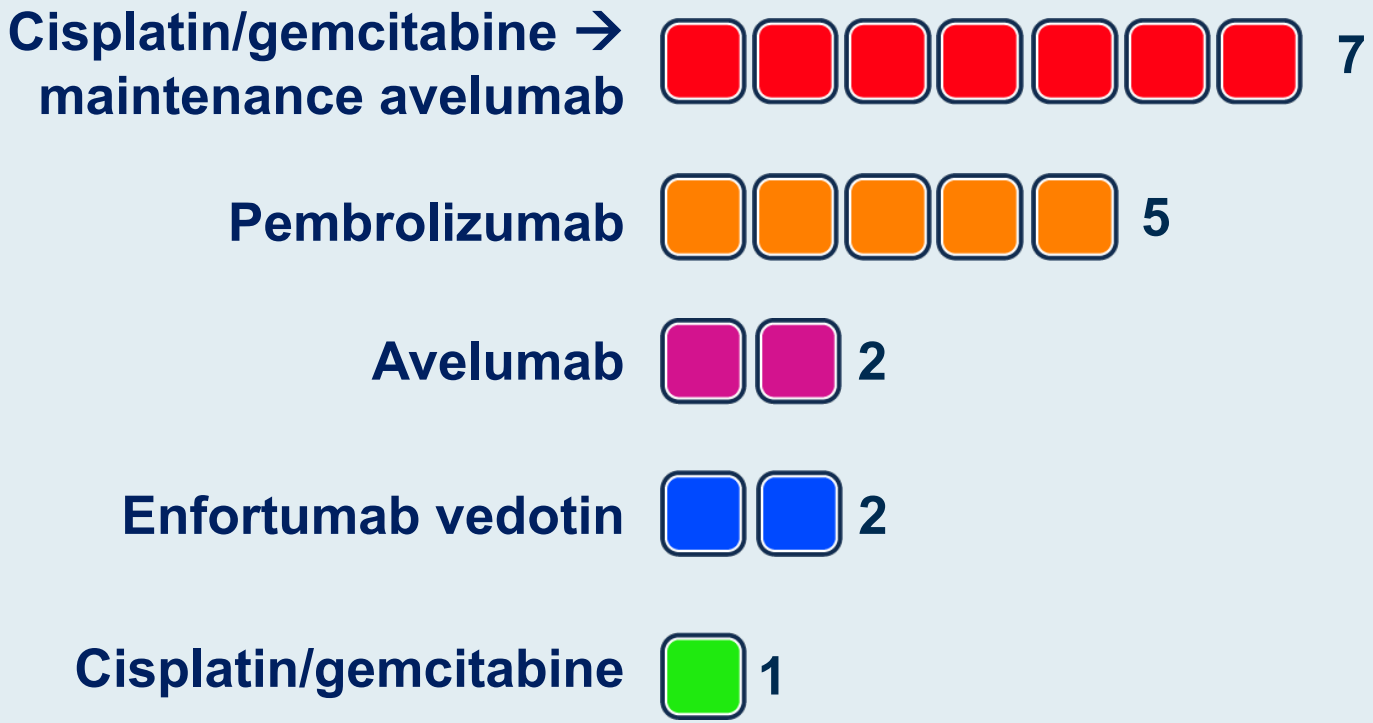
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 9 months after cystectomy and adjuvant nivolumab for muscle-invasive FGFR wild-type UBC?



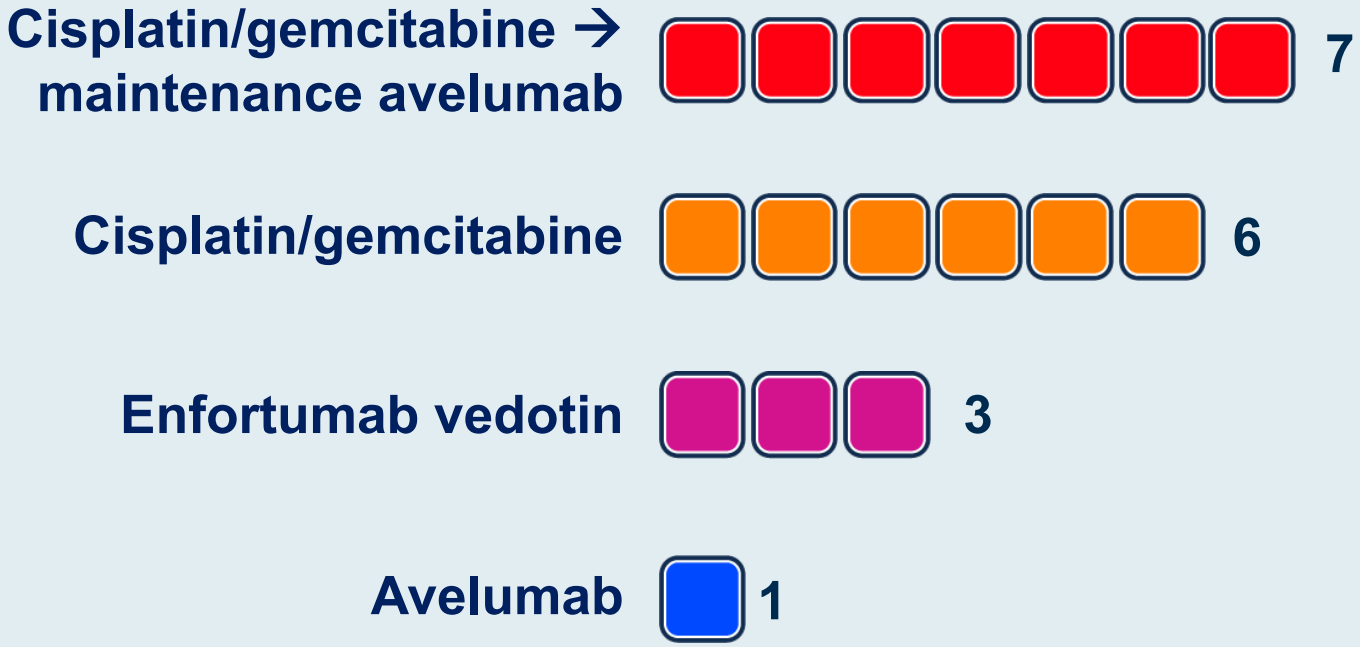
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 18 months after cystectomy and adjuvant gemcitabine/cisplatin for muscle-invasive FGFR wild-type UBC?



Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 18 months after cystectomy and adjuvant nivolumab for muscle-invasive FGFR wild-type UBC?

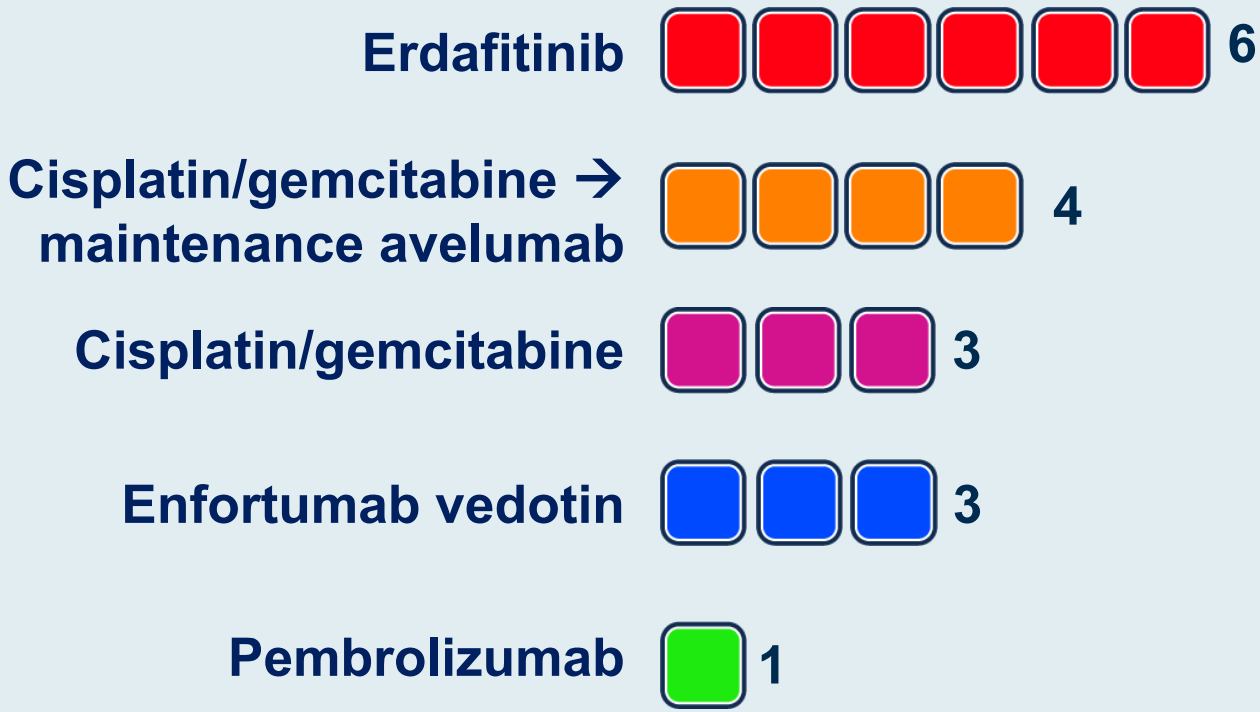


Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 9 months after cystectomy and adjuvant gemcitabine/cisplatin for muscle-invasive UBC and is found to have an FGFR3 mutation?

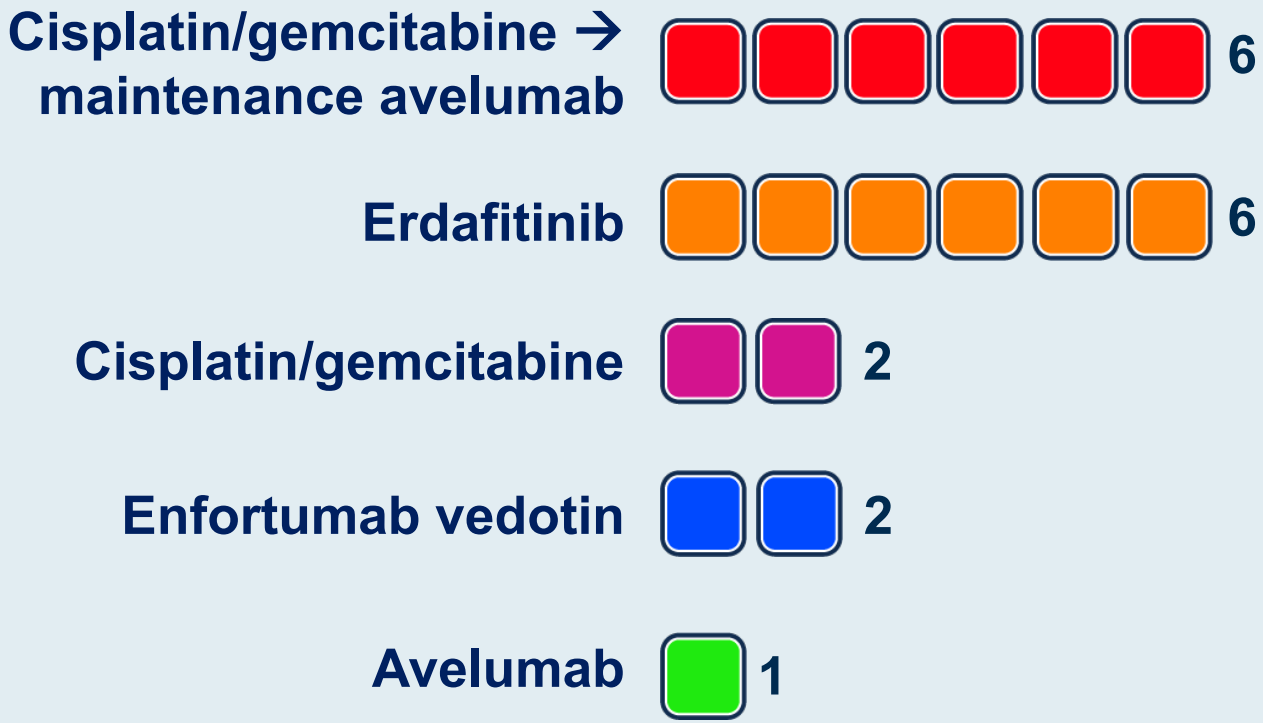
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 9 months after cystectomy and adjuvant nivolumab for muscle-invasive UBC and is found to have an FGFR3 mutation?



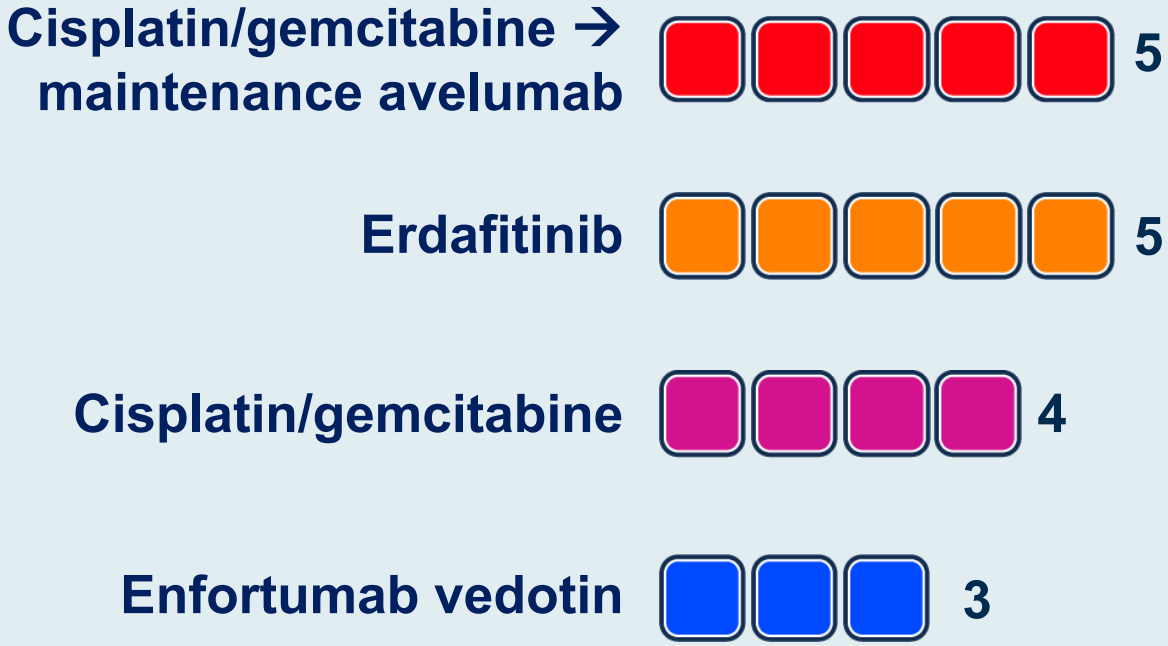
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 18 months after cystectomy and adjuvant gemcitabine/cisplatin for muscle-invasive UBC and is found to have an FGFR3 mutation?



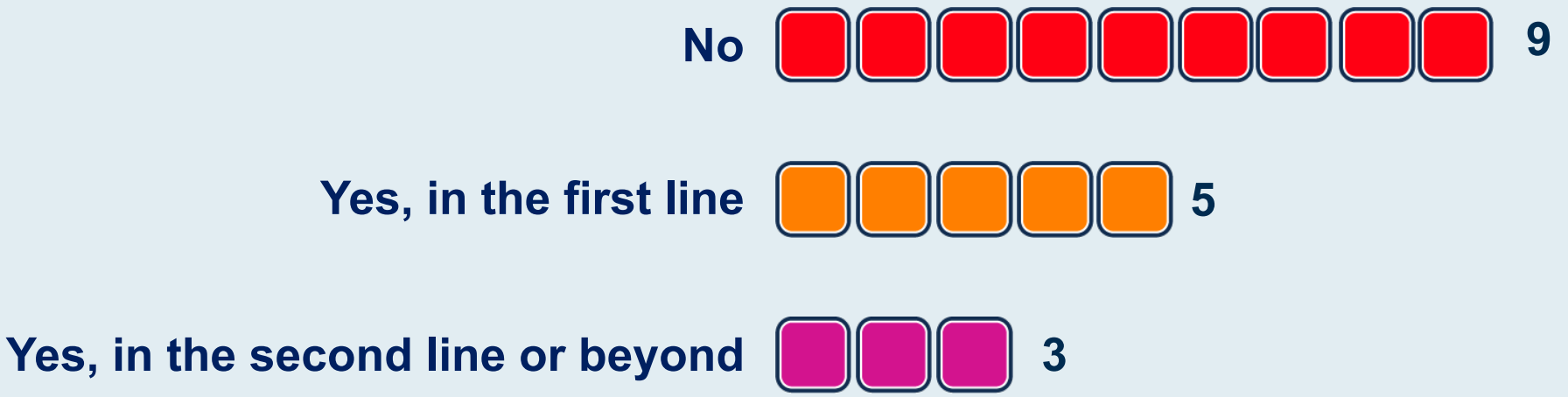
Survey of genitourinary cancer clinical investigators

What would you generally recommend for a 65-year-old patient who experiences disease recurrence in the liver 18 months after cystectomy and adjuvant nivolumab for muscle-invasive UBC who is found to have an FGFR3 mutation?



Survey of genitourinary cancer clinical investigators

Regulatory and reimbursement issues aside, would you administer pembrolizumab in combination with enfortumab vedotin to a patient with metastatic UBC outside of a protocol setting?

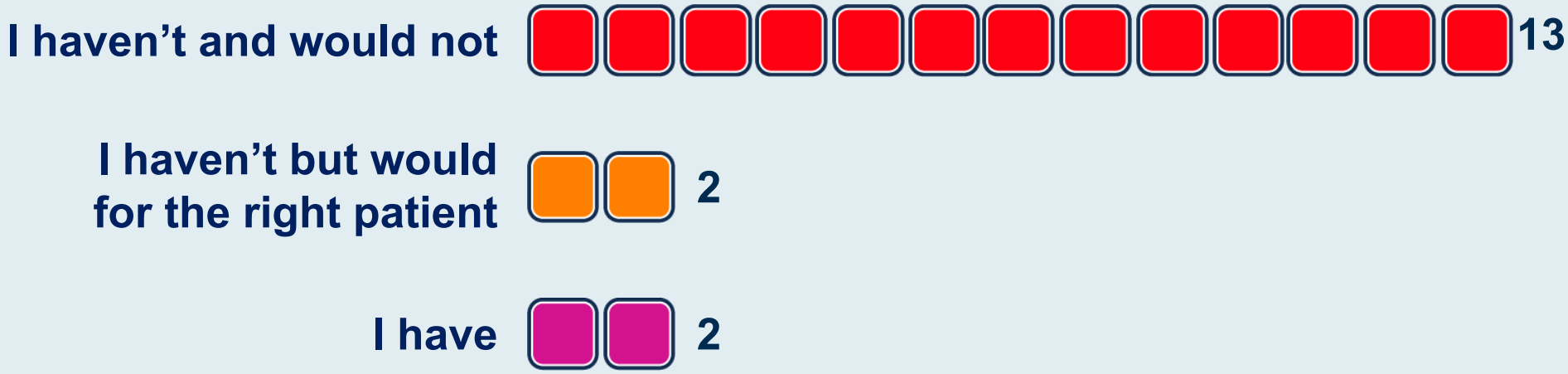


Survey of genitourinary cancer clinical investigators

Based on current clinical trial data and your personal experience, do you believe pembrolizumab in combination with enfortumab vedotin will result in superior outcomes compared to currently available up-front regimens for metastatic UBC?

Survey of genitourinary cancer clinical investigators

Have you administered or would you administer an anti-PD-1/ PD-L1 antibody in combination with an anti-CTLA-4 antibody to a patient with newly diagnosed metastatic UBC outside of a protocol setting?



Survey of genitourinary cancer clinical investigators

In which subsets of patients with newly diagnosed metastatic UBC would you be inclined to prioritize the use of an anti-PD-1/ PD-L1 antibody in combination with an anti-CTLA-4 antibody?

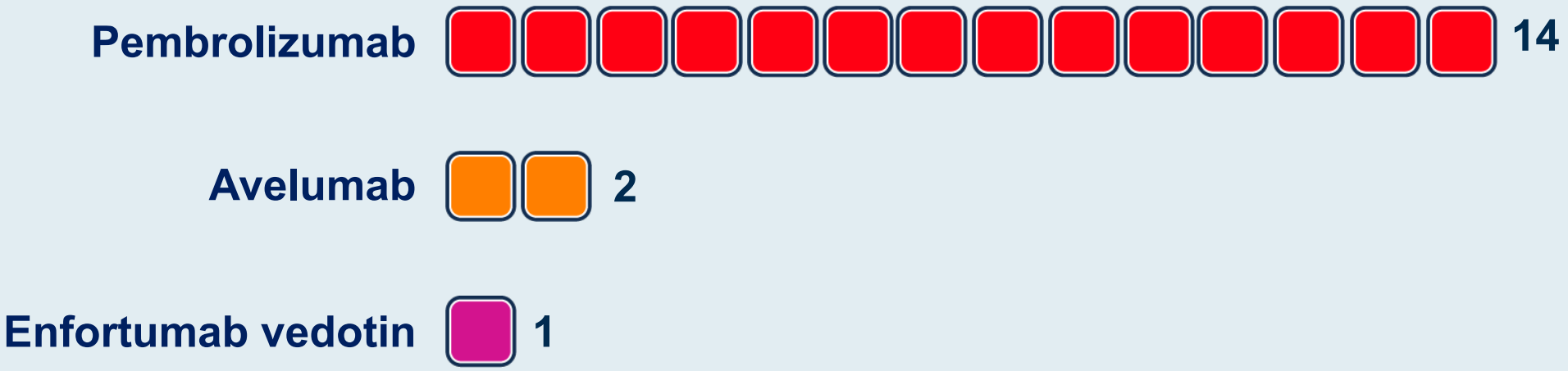
- None
- High TMB, high PD-L1, no liver mets, low volume disease,
- PD-L1+
- Biomarker patients
- High mutational burden PD-L1+
- Depends on CM901 & NILE trials data
- Low disease burden. PS 0. non visceral
- None
- Don’t know
- Younger and healthier patients/poor prognosis disease
- None
- Need more data

In which subsets of patients with newly diagnosed metastatic UBC would you be inclined to prioritize the use of an anti-PD-1/PD-L1 antibody in combination with an anti-CTLA-4 antibody? (Continued)

- Patients with advanced or metastatic urothelial carcinoma and with progression on prior platinum-based drugs
- Patients with optimal performance status and minimal comorbidities
- Very high risk and cisplatin ineligible
- Protocol only
- PD-L1 high or those without other options and are fit and without prior severe autoimmunity

MODULE 3: Selection and Sequencing of Therapy for Relapsed/Refractory mUBC — Dr Petrylak

What would you generally recommend as second-line therapy for a 65-year-old patient with FGFR wild-type UBC metastatic to the liver whose disease progresses on first-line cisplatin/gemcitabine?

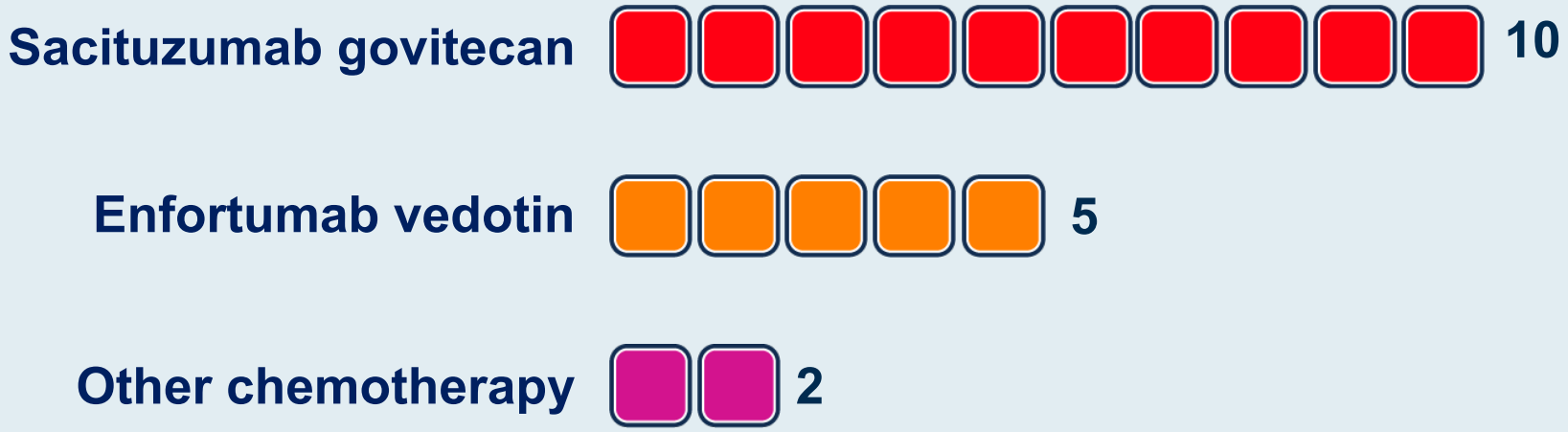


Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for a 65-year-old patient with FGFR wild-type UBC metastatic to the liver whose disease progresses on first-line cisplatin/gemcitabine followed by avelumab maintenance?

Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for a 65-year-old patient with a history of poorly controlled diabetes and FGFR wild-type UBC metastatic to the liver whose disease progresses on first-line cisplatin/gemcitabine followed by avelumab maintenance?

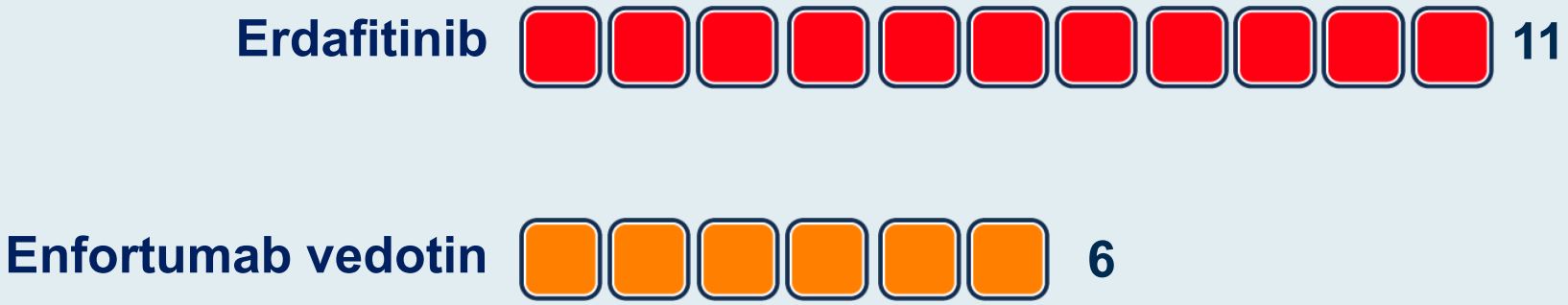


Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for a 65-year-old patient with FGFR3 mutation-positive UBC metastatic to the liver whose disease progresses on first-line cisplatin/gemcitabine?

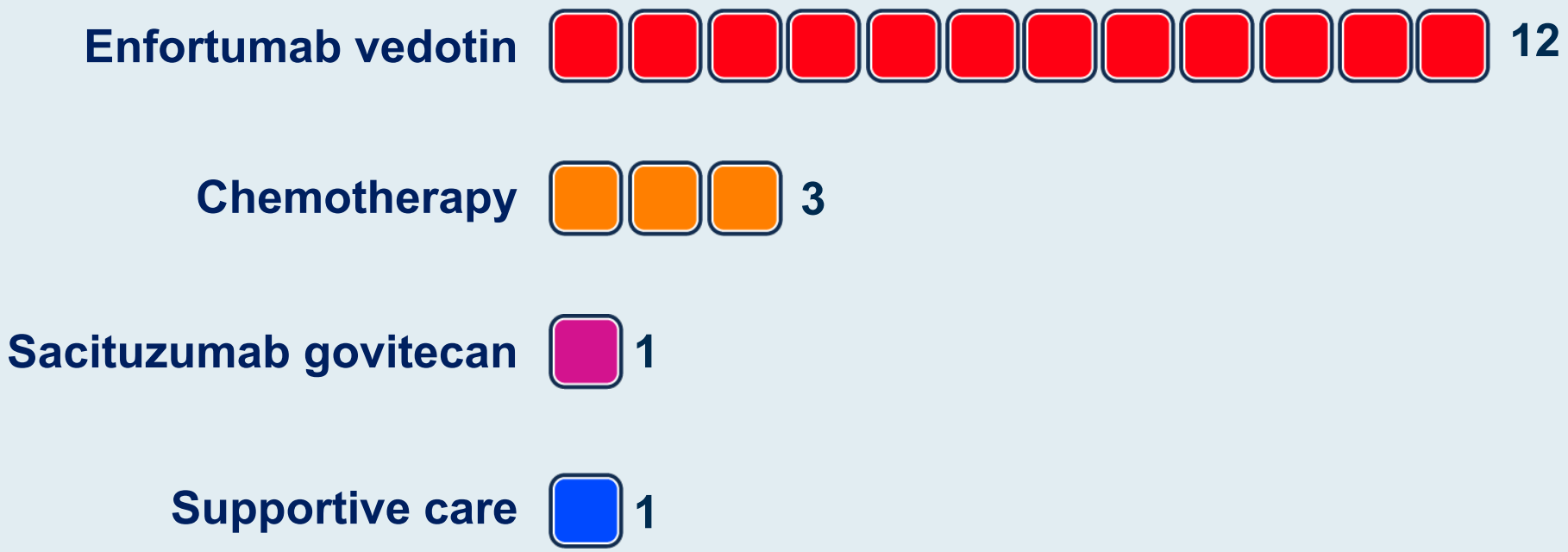
Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for a 65-year-old patient with FGFR3 mutation-positive UBC metastatic to the liver whose disease progresses on first-line cisplatin/gemcitabine followed by avelumab maintenance?



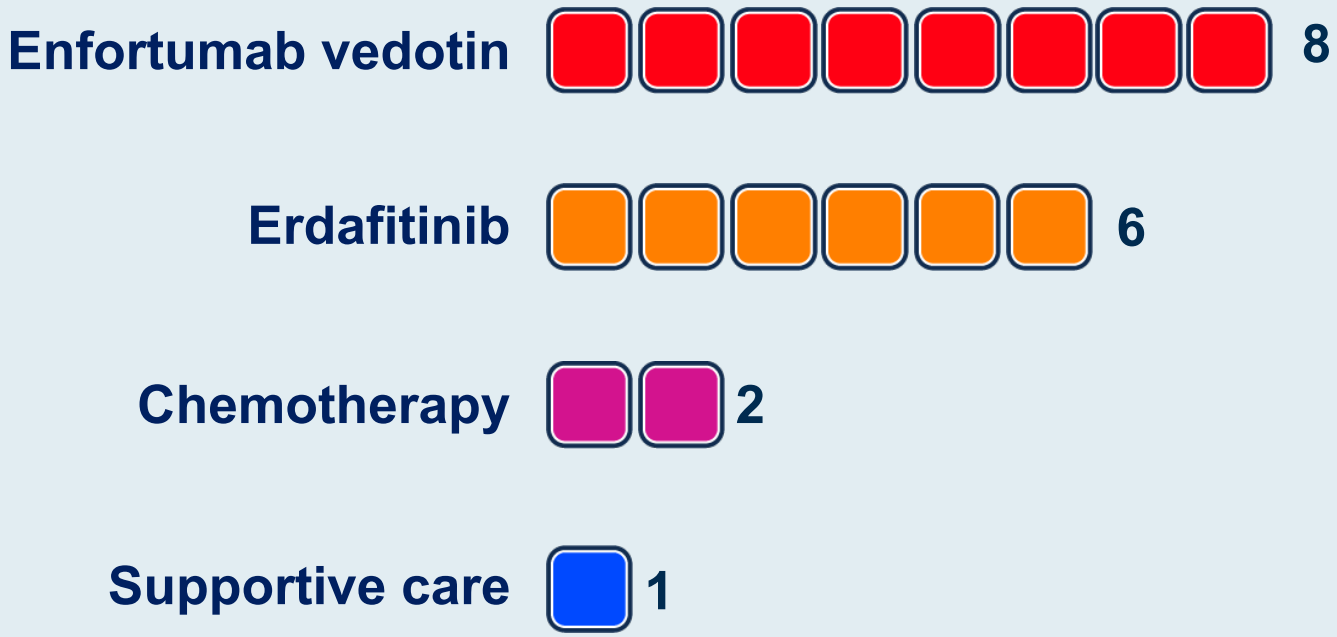
Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for an 80-year-old patient with FGFR wild-type UBC metastatic to the liver whose disease progresses on first-line pembrolizumab?



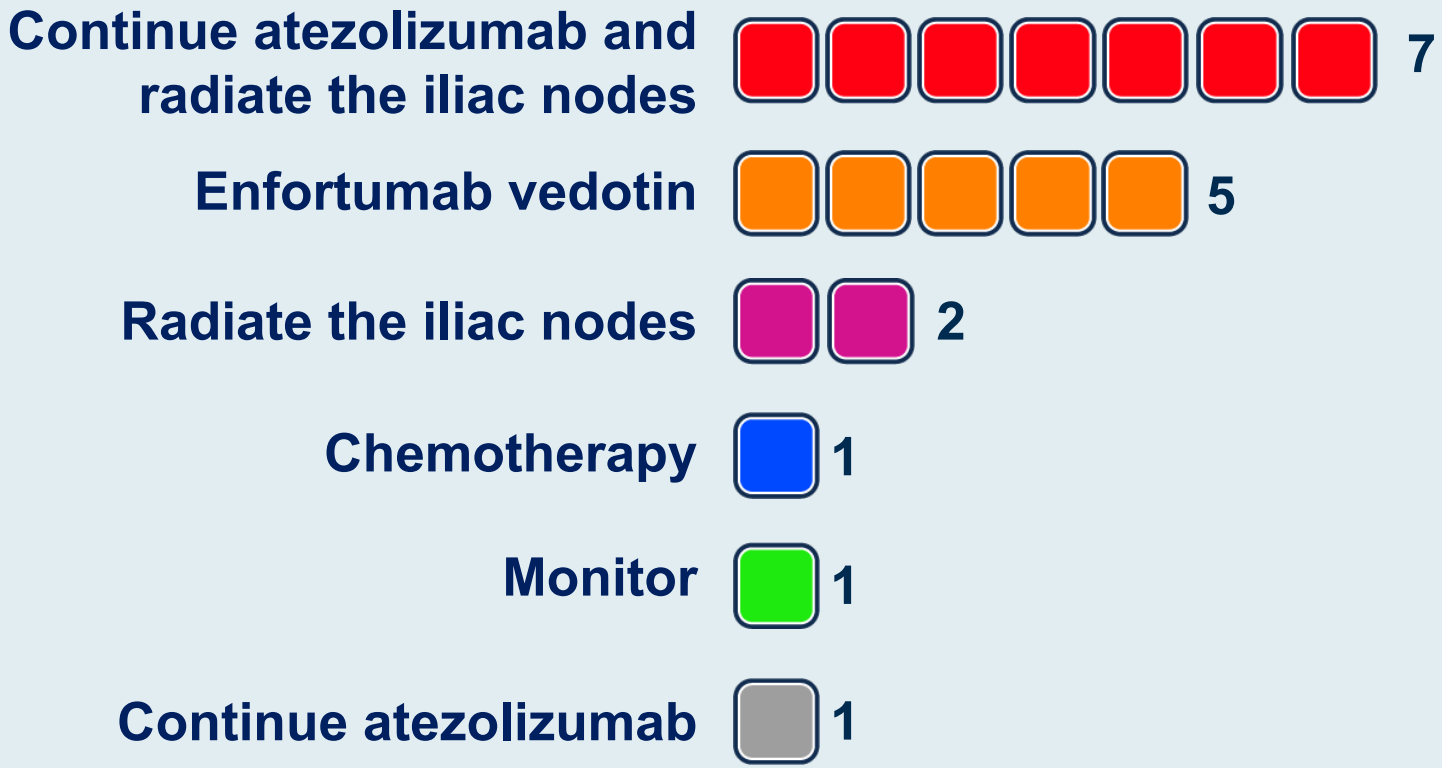
Survey of genitourinary cancer clinical investigators

What would you generally recommend as second-line therapy for an 80-year-old patient with FGFR3 mutation-positive UBC metastatic to the liver whose disease progresses on first-line pembrolizumab?



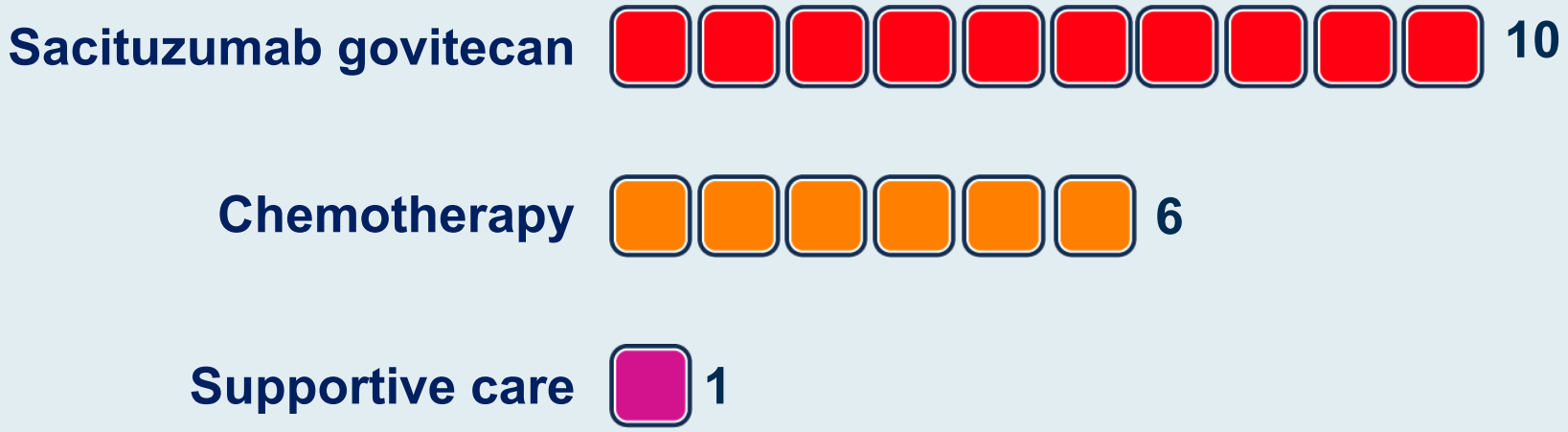
Survey of genitourinary cancer clinical investigators

An 85-year-old man (PS = 2) presents with FGFR wild-type de novo metastatic UBC to the nodes and bone and receives atezolizumab with stable disease followed by slow disease progression in the iliac nodes only. What would you recommend?



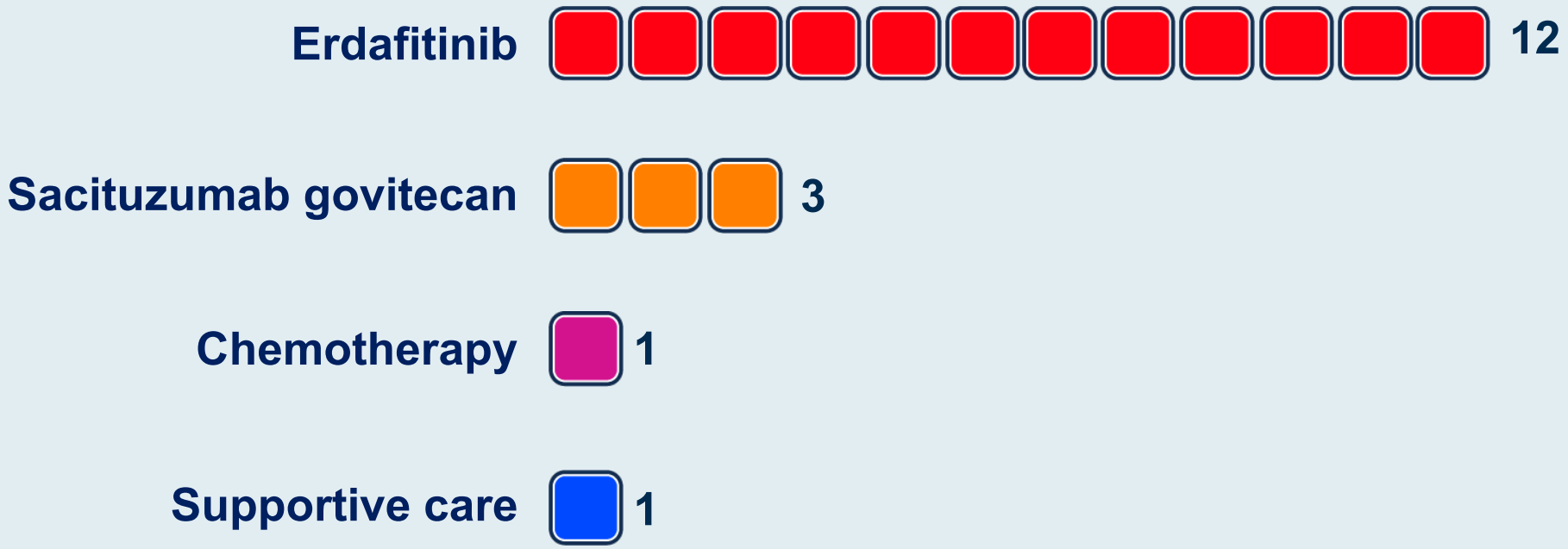
Survey of genitourinary cancer clinical investigators

What would you generally recommend as third-line therapy for an 80-year-old patient with FGFR wild-type metastatic UBC whose disease has progressed on first-line pembrolizumab and second-line enfortumab vedotin?



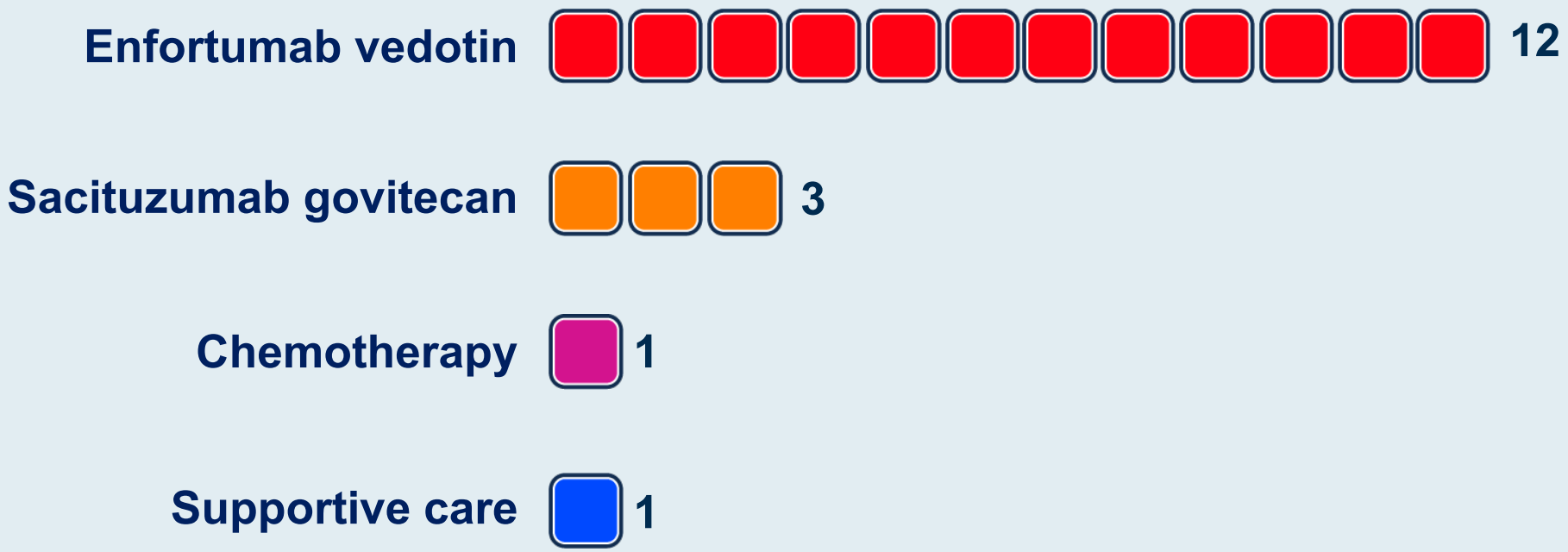
Survey of genitourinary cancer clinical investigators

What would you generally recommend as third-line therapy for an 80-year-old patient with FGFR3 mutation-positive metastatic UBC whose disease has progressed on first-line pembrolizumab and second-line enfortumab vedotin?



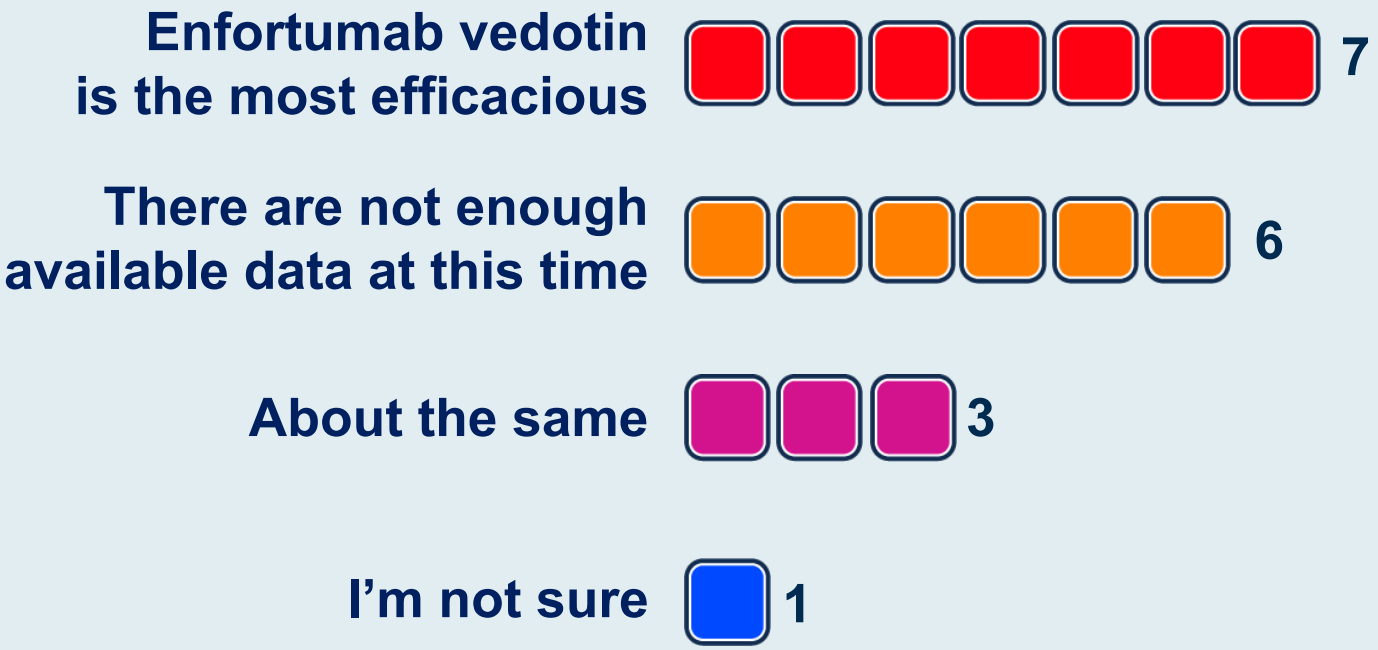
Survey of genitourinary cancer clinical investigators

What would you generally recommend as third-line therapy for an 80-year-old patient with FGFR3 mutation-positive metastatic UBC whose disease has progressed on first-line pembrolizumab and second-line erdafitinib?



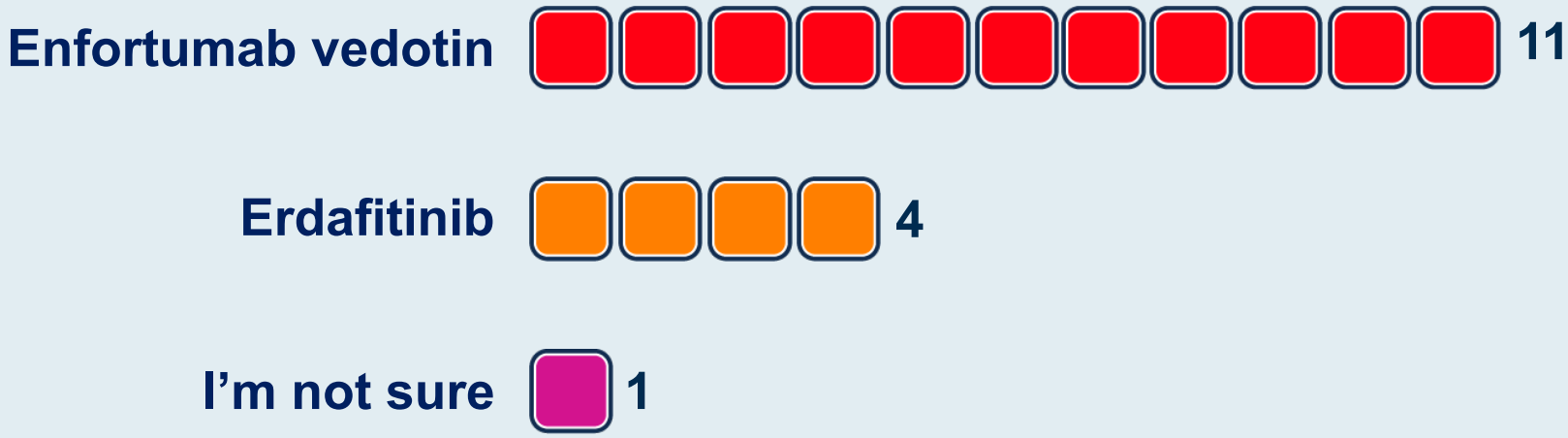
Survey of genitourinary cancer clinical investigators

Based on current clinical trial data and your personal experience, how would you evaluate the global efficacy of enfortumab vedotin, erdafitinib and sacituzumab govitecan in patients with metastatic UBC?



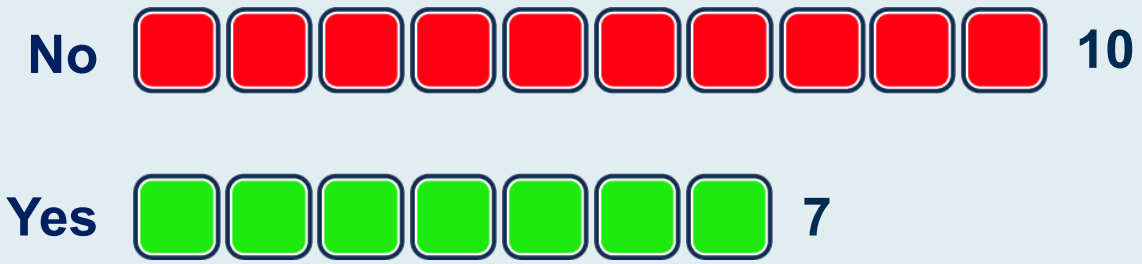
Survey of genitourinary cancer clinical investigators

Which of the following would you generally recommend first for a patient with metastatic UBC who is eligible to receive all 3 agents?



Survey of genitourinary cancer clinical investigators

Do you generally conduct HER2 testing for your patients with metastatic UBC?

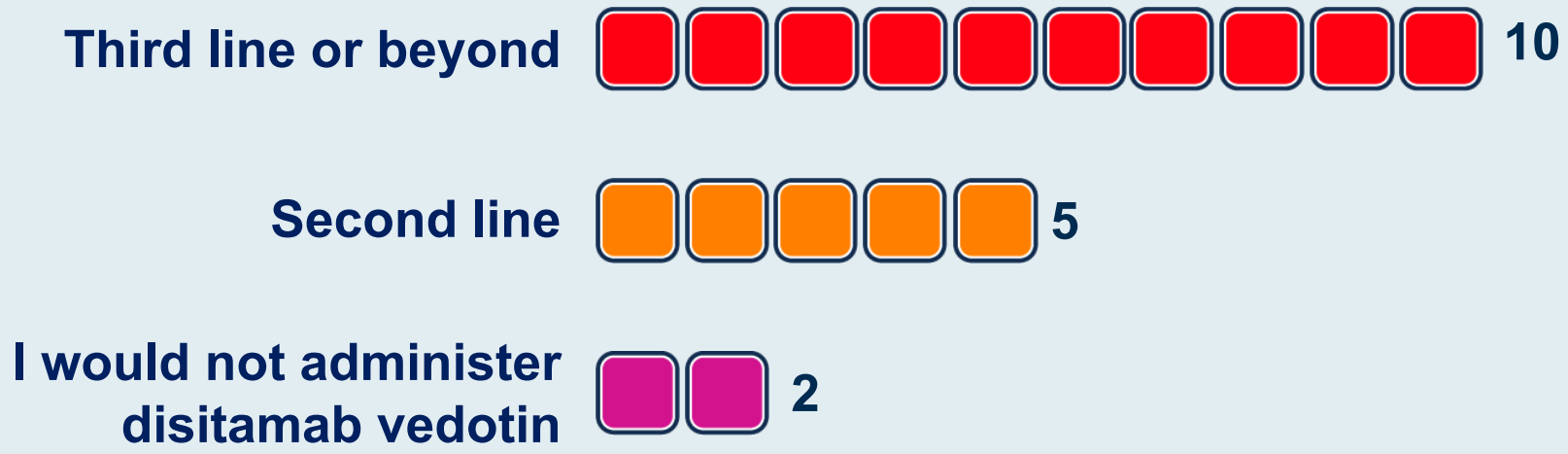


Survey of genitourinary cancer clinical investigators

Do you generally offer HER2-targeted therapy to your patients with HER2-positive metastatic UBC outside of a protocol setting?

Survey of genitourinary cancer clinical investigators

If disitamab vedotin were available for patients with HER2-positive metastatic UBC, in which line of therapy would you like to use it?

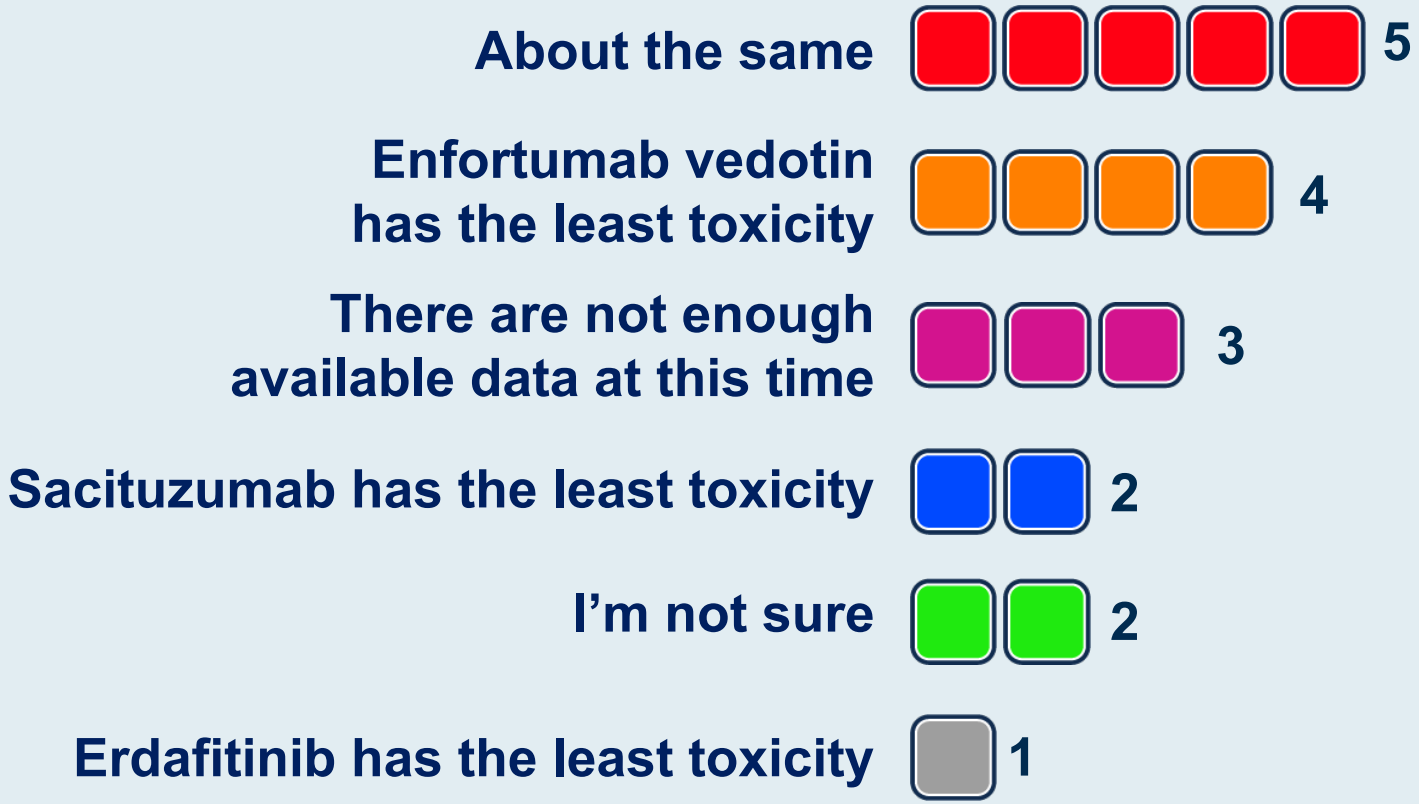


Survey of genitourinary cancer clinical investigators

MODULE 4: Tolerability/Toxicity of Novel Treatment Strategies and Practical Considerations in the Management of UBC — Dr Sonpavde

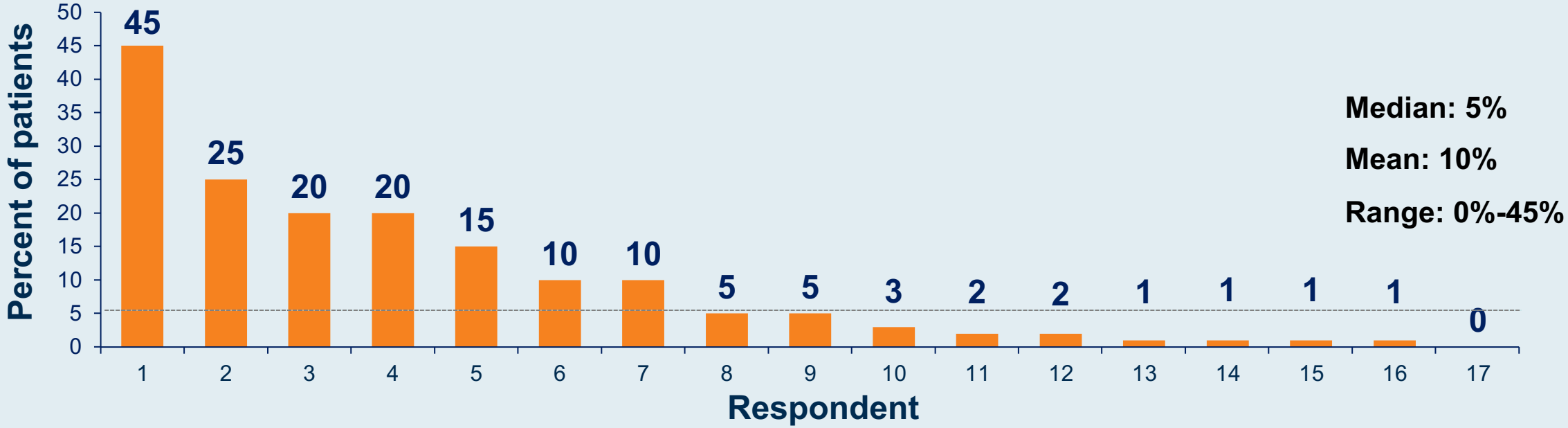
RTP
RESEARCH
TO PRACTICE

Based on current clinical trial data and your personal experience, how would you compare the global tolerability/toxicity of enfortumab vedotin, erdafitinib and sacituzumab govitecan in patients with metastatic UBC?

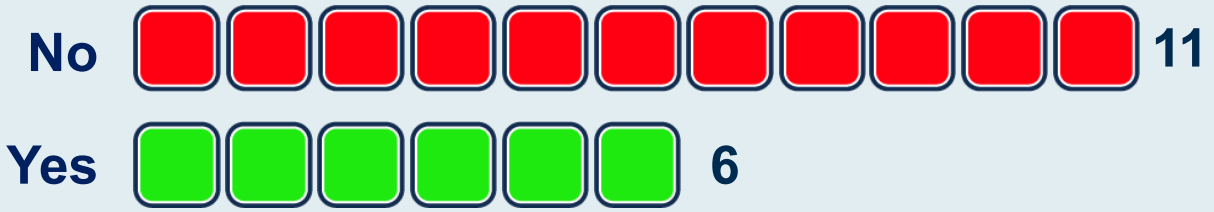


Survey of genitourinary cancer clinical investigators

Approximately what proportion of your patients with metastatic UBC receiving enfortumab vedotin develop clinically significant ocular toxicity?

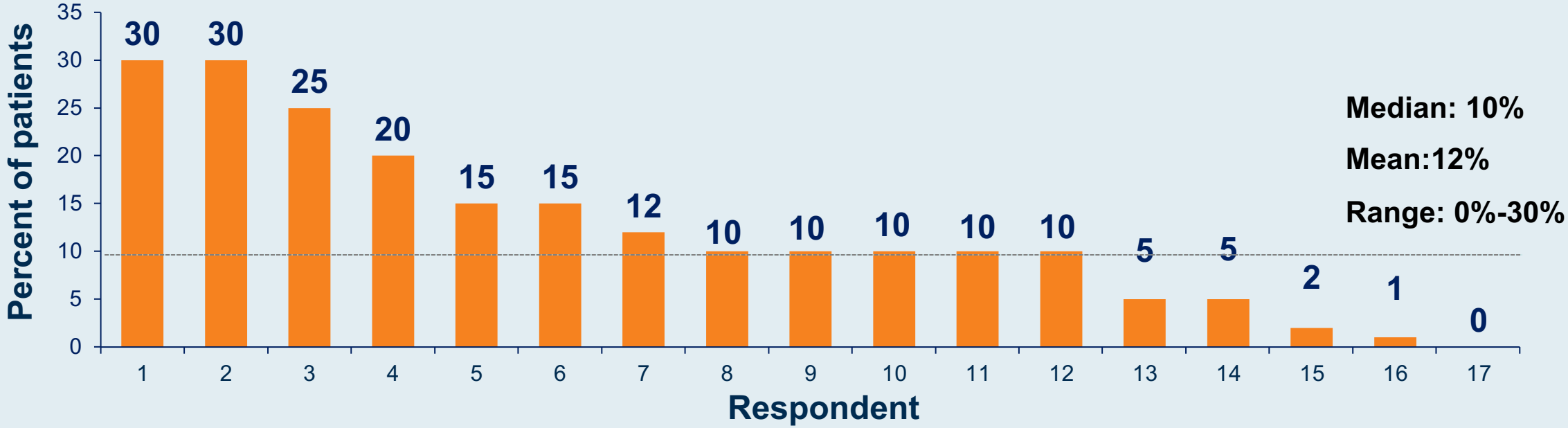


Do you recommend regular ophthalmologic examinations to your patients with metastatic UBC receiving enfortumab vedotin?



Survey of genitourinary cancer clinical investigators

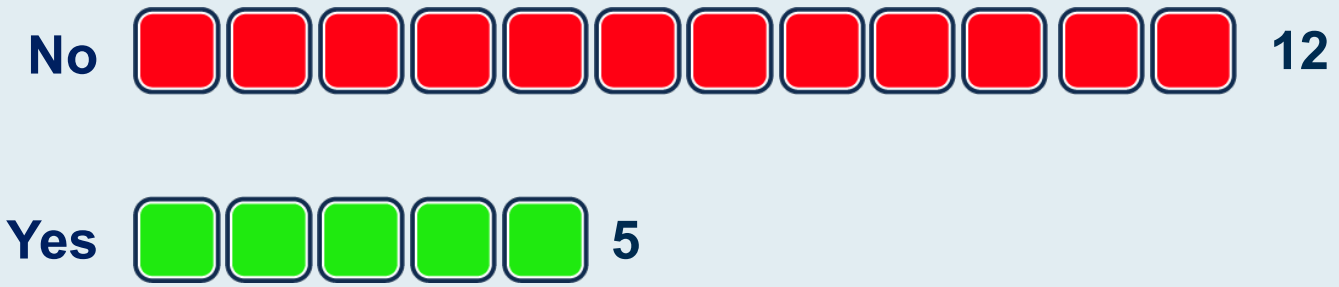
Approximately what proportion of your patients with metastatic UBC receiving erdafitinib develop clinically significant ocular toxicity?



Do you recommend regular ophthalmologic examinations to your patients with metastatic UBC receiving erdafitinib?

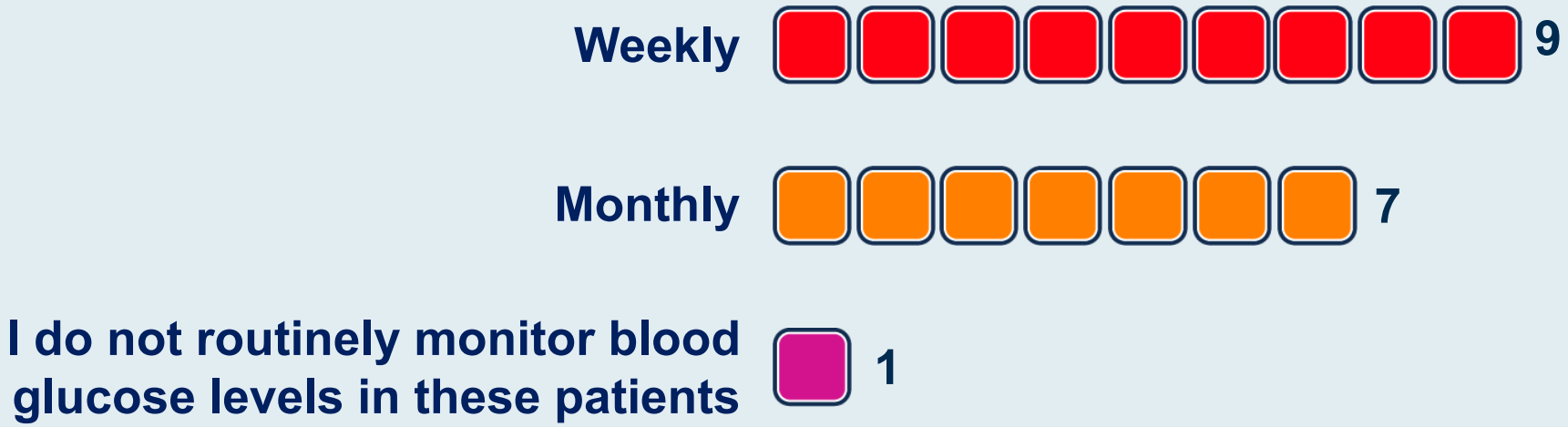
Survey of genitourinary cancer clinical investigators

Have you encountered serious skin reactions such as Stevens-Johnson syndrome/toxic epidermal necrolysis in any of your patients with metastatic UBC receiving enfortumab vedotin?



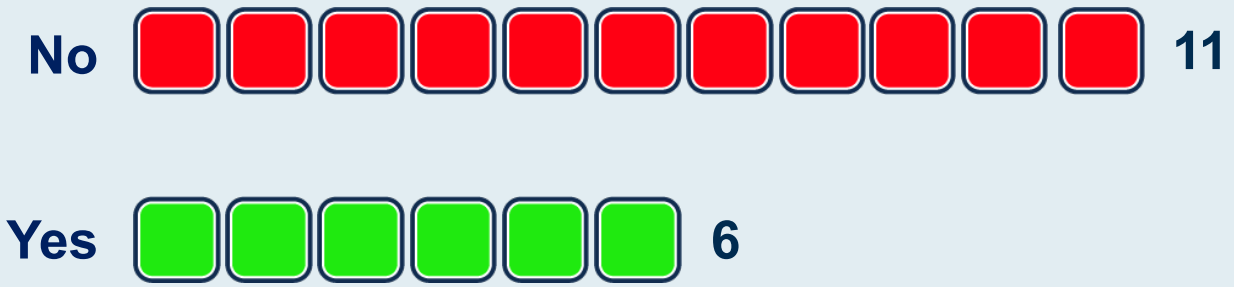
Survey of genitourinary cancer clinical investigators

How frequently do you monitor blood glucose levels in your patients with metastatic UBC receiving enfortumab vedotin?



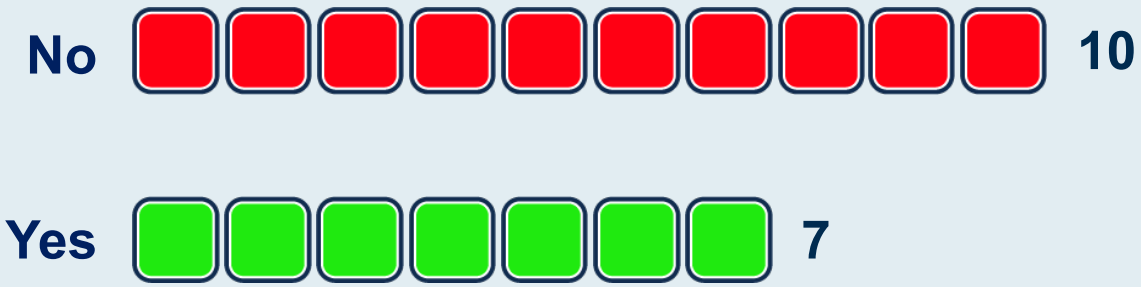
Survey of genitourinary cancer clinical investigators

Is there a baseline Hgb A1C level beyond which you would not consider treating a patient with metastatic UBC with enfortumab vedotin?



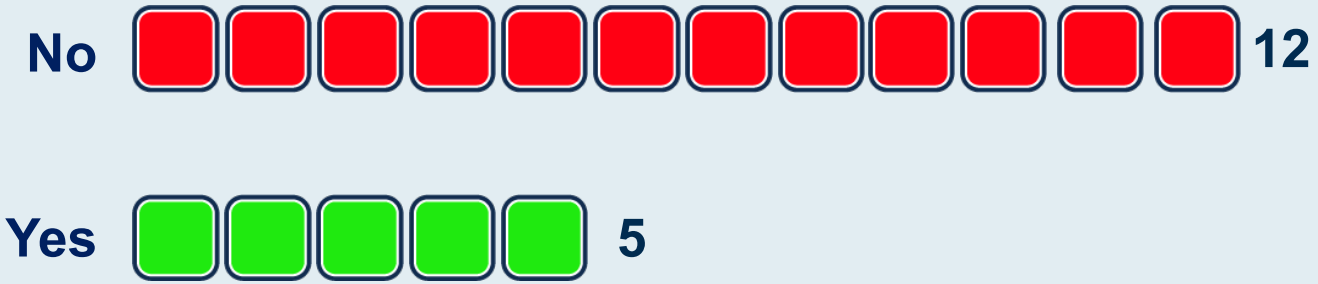
Survey of genitourinary cancer clinical investigators

In general, when you administer erdafitinib, do you preemptively prescribe steroid mouthwash for the prevention of treatment-related stomatitis?



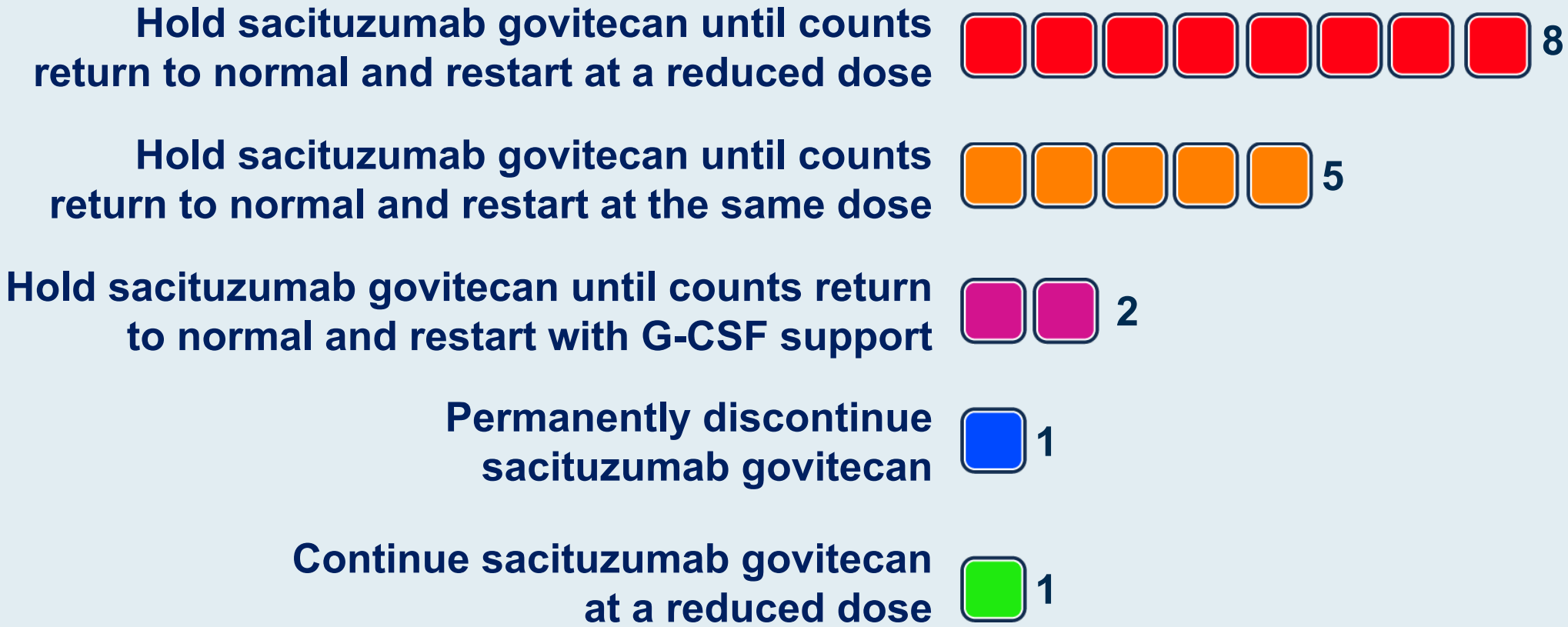
Survey of genitourinary cancer clinical investigators

In general, when you administer sacituzumab govitecan for metastatic UBC, do you preemptively prescribe growth factors for the prevention of treatment-related neutropenia?



Survey of genitourinary cancer clinical investigators

A patient who is experiencing a good response to sacituzumab govitecan for metastatic UBC is found to have an absolute neutrophil count of 900/mm^3 without fever. What would you recommend?

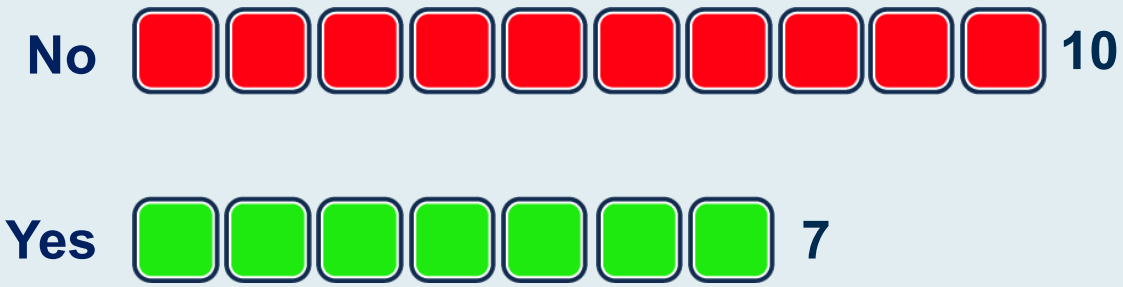


Survey of genitourinary cancer clinical investigators

In general, when you administer sacituzumab govitecan for metastatic UBC, do you initiate preemptive medication for nausea and vomiting?

Survey of genitourinary cancer clinical investigators

In general, when you administer sacituzumab govitecan for metastatic UBC, do you initiate preemptive medication for diarrhea?



Survey of genitourinary cancer clinical investigators