



PRACTICE AID

# Kidney Cancer: Patient-Centered Research and Patient Voices<sup>1</sup>

Full abbreviations, accreditation, and disclosure information available at [PeerView.com/GHE40](https://www.peerview.com/GHE40)

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## KCCure's Research Helps Inform Providers of the Patient Voice

The Kidney Cancer Research Alliance (KCCure) provides answers to questions that patients and caregivers are asking.

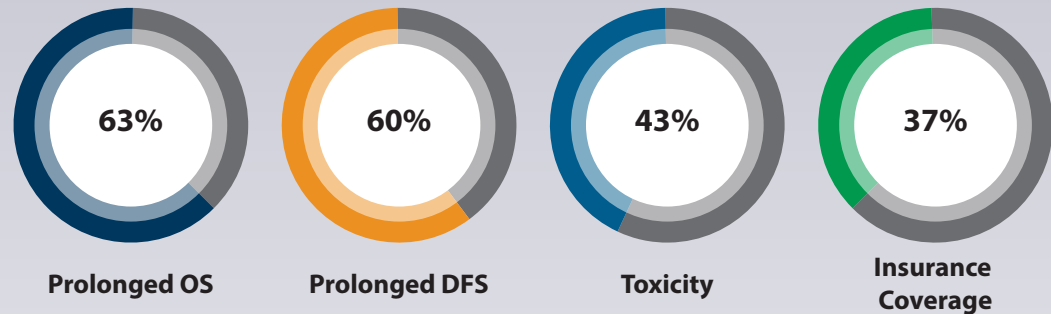
Wherever they are in their diagnosis, patients can visit

**kccure.org**

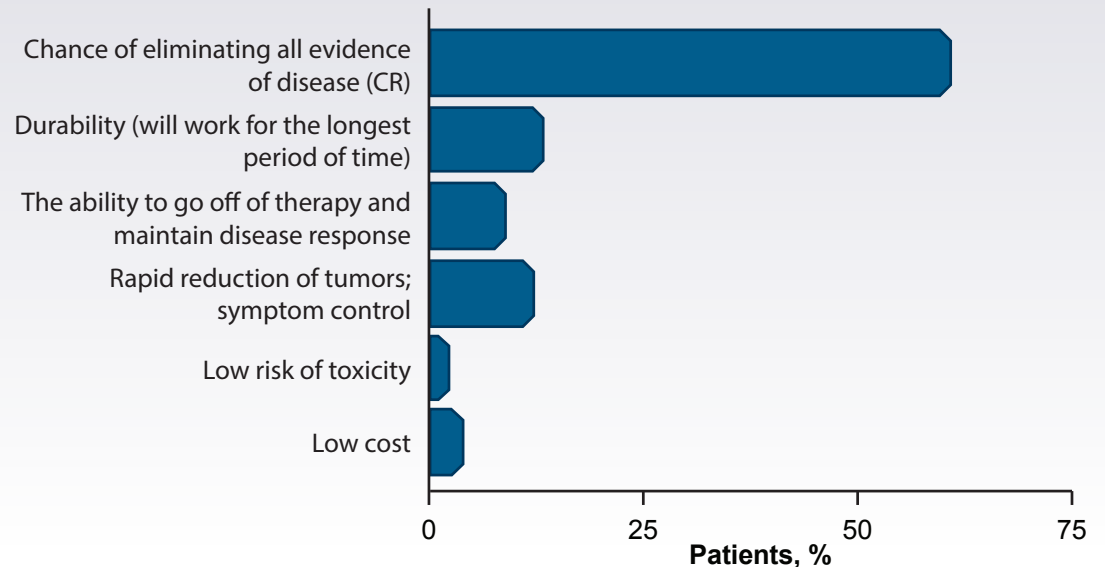
to find updated information on different types of kidney cancer, new treatment options, and more.

KCCure also conducts its own patient-centered research aimed at improving the quality of life of all patients with kidney cancer by better identifying and defining patients' needs and concerns.

## Patients reported what they believed was the most important consideration in their treatment choice<sup>2</sup>



## When patients were asked to state the most important desire or outcome they wanted from treatment, they overwhelmingly chose a complete response and were less focused on other items<sup>3</sup>





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## Patient Voices

<https://kccure.org/category/patient-stories>

When faced with a new cancer diagnosis, patients experience grief, loss of control, and feelings of isolation according to KCCure's research. To help combat the emotional toll of cancer, the organization encourages patients to connect and share their stories with each other. These actions can help families affected by kidney cancer feel less alone, and they are an important component of survivorship.

### Julia

"I find if you ask 3 doctors, you will get 4 different opinions. It definitely did not make things easier. It felt like too heavy a decision to make myself. The first time I based my decision on what most of the doctors were leaning toward. The second time, I decided based on the doctor whom I felt safest with. So in the end, it was a matter of trust."

### Teresa

"I had a complete response with [an IO + TKI]. I stopped the [IO] but still take [the TKI]. My doctor has mentioned several times I could come off but I'm terrified to stop taking it."

### Larry

"I was fighting for immunotherapy since I had mets from the kidney to lung and brain. But the only option I was given was [an IO + TKI]. Reading up on them I felt good about it, but I wasn't given any other choices."

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KCCure provides patient perspectives on surgery, adjuvant therapy, treatment anxiety, and much more. Visit [kccure.org](https://www.kccure.org) to access patient support communities and other helpful resources.

1. <https://www.kccure.org>. 2. Battle D et al. *J Clin Oncol*. 2018;36(6\_suppl):644. 3. Battle D et al. 2020 American Society of Clinical Oncology Annual Meeting (ASCO 2020). Abstract 5083.

## IO + IO Combination Regimen

### **Nivolumab + Ipilimumab<sup>1,2</sup>**

Approved April 2018 for intermediate- or poor-risk disease based on the phase 3 CheckMate -214 trial  
NCCN<sup>3</sup> category 1 for intermediate or poor risk (preferred); category 2A for favorable risk (other recommended regimen)

Nivolumab 3 mg/kg followed by ipilimumab 1 mg/kg on the same day every 3 wk for 4 doses, then nivolumab 240 mg every 2 wk or 480 mg every 4 wk as a single agent

## IO + VEGFR TKI Combination Regimens

### **Pembrolizumab + Axitinib<sup>4,5</sup>**

Approved April 2019 in all IMDC groups based on the phase 3 KEYNOTE-426 trial  
NCCN<sup>3</sup> category 1 for intermediate or poor risk (preferred); category 2A for favorable risk (preferred)

Pembrolizumab 200 mg every 3 wk or 400 mg every 6 wk in combination with axitinib 5 mg PO twice daily

### **Avelumab + Axitinib<sup>5,6</sup>**

Approved May 2019 in all IMDC groups based on the phase 3 JAVELIN Renal 101 trial  
NCCN<sup>3</sup> category 2A for all risk groups (other recommended regimen)

Avelumab 800 mg every 2 wk in combination with axitinib 5 mg PO twice daily

### **Nivolumab + Cabozantinib<sup>1,7</sup>**

Approved January 2021 in all IMDC groups based on the phase 3 CheckMate -9ER trial  
NCCN<sup>3</sup> category 1 for all risk groups (preferred)

Nivolumab 240 mg every 2 wk or 480 mg every 4 wk in combination with cabozantinib 40 mg once daily without food

### **Pembrolizumab + Lenvatinib<sup>4,8</sup>**

Under priority review March 2021 based on the phase 3 CLEAR trial  
NCCN<sup>3</sup> category 1 for all risk groups (preferred)

Pembrolizumab 200 mg IV every 3 wk in combination with lenvatinib 20 mg PO once daily<sup>9</sup>

## Selected Phase 3 Trials in the First-Line Setting<sup>10</sup>

### **PDIGREE (NCT03793166)**

Nivolumab + ipilimumab → nivolumab vs nivolumab + ipilimumab → nivolumab + cabozantinib

### **COSMIC-313 (NCT03937219)**

Cabozantinib + nivolumab + ipilimumab vs placebo + nivolumab + ipilimumab

### **PIVOT-09 (NCT03729245)**

NKTR-214 + nivolumab vs cabozantinib or sunitinib

### **NCT03873402**

Nivolumab + ipilimumab vs nivolumab

### **IMmotion151 (NCT02420821)**

Atezolizumab + bevacizumab vs sunitinib



# Current Approvals and Future Directions in RCC Therapy

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Pretreated Advanced Disease

## IO Regimen

### Nivolumab<sup>1</sup>

Approved November 2015 in patients who have received prior anti-angiogenic therapy based on the phase 3 CheckMate -025 trial NCCN<sup>3</sup> category 1 (preferred)

Nivolumab 240 mg every 2 wk or 480 mg every 4 wk

## VEGFR TKI Regimens

### Cabozantinib<sup>7</sup>

Approved April 2016 based on the phase 3 METEOR trial NCCN<sup>3</sup> category 1 (preferred)

Cabozantinib 60 mg PO once daily without food

### Lenvatinib + Everolimus<sup>8,11</sup>

Approved May 2016 in patients with advanced RCC following one prior anti-angiogenic therapy based on the phase 2 HOPE 205 trial NCCN<sup>3</sup> category 1 (other recommended regimen)

Lenvatinib 18 mg PO once daily with everolimus 5 mg PO once daily; modify the recommended daily dose for certain patients with renal or hepatic impairment

### Tivozanib<sup>12</sup>

Approved March 2021 in patients with relapsed or refractory advanced RCC following >2 prior systemic therapies based on the phase 3 TIVO-3 trial NCCN<sup>3</sup> category 2A (other recommended regimen)

Tivozanib 1.34 mg once daily with or without food for 21 d on treatment followed by 7 d off treatment (28-d cycle)

## VEGFR TKI Regimen

### Sunitinib<sup>13</sup>

Approved November 2017 in adult patients at high risk of recurrence following nephrectomy based on the phase 3 S-TRAC trial NCCN<sup>3</sup> category 2A (other recommended regimen)

Sunitinib 50 mg PO once daily with or without food, 4 wk on treatment followed by 2 wk off treatment for nine 6-wk cycles

## Selected Phase 3 Trials in the Later-Line Setting<sup>10</sup>

**CONTACT-03 (NCT04338269)**  
Atezolizumab + cabozantinib vs cabozantinib

**NCT04195750**  
Belzutifan vs everolimus

**NCT04586231**  
Belzutifan + lenvatinib vs cabozantinib

## Selected Phase 3 Trials in the Adjuvant Setting<sup>10</sup>

**KEYNOTE-564 (NCT03142334)**  
Pembrolizumab vs placebo  
**Primary endpoint met!**<sup>14</sup>

**CheckMate -914 (NCT03138512)**  
Nivolumab ± ipilimumab vs placebo

**RAMPART (NCT03288532)**  
Durvalumab ± tremelimumab vs active surveillance

**PROSPER RCC (NCT03055013)**  
Nivolumab + nephrectomy vs nephrectomy

**IMmotion010 (NCT03024996)**  
Atezolizumab vs placebo

Adjuvant Setting

1. Opdivo (nivolumab) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/125554s092lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125554s092lbl.pdf). 2. Yervoy (ipilimumab) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/125377s121lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125377s121lbl.pdf). 3. NCCN Clinical Practice Guidelines in Oncology. *Kidney Cancer*. Version 4.2021. [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf). 4. Keytruda (pembrolizumab) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/125514s097lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125514s097lbl.pdf). 5. Inlyta (axitinib) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/202324s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202324s011lbl.pdf). 6. Bavencio (avelumab) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761049s005lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761049s005lbl.pdf). 7. Cabometyx (cabozantinib) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208692s010lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208692s010lbl.pdf). 8. Lenvima (lenvatinib) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/206947s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206947s018lbl.pdf). 9. Motzer R et al. *N Engl J Med* 2021; 384:1289-1300. 10. <https://clinicaltrials.gov>. 11. Afinitor (everolimus) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/022334s047,203985s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022334s047,203985s020lbl.pdf). 12. Fotivda (tivozanib) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212904s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212904s000lbl.pdf). 13. Sutent (sunitinib malate) Prescribing Information. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/021938s037lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021938s037lbl.pdf). 14. Choueiri TK et al. 2021 American Society of Clinical Oncology Annual Meeting (ASCO 2021). Abstract LBA5.