

## Smilow Update: April 26, 2021

Dear Colleagues,

### **Radiation Oncology Update**

Last week, we let you know that our radiation oncology vendor Elekta's software MOSAIQ was negatively impacted by a cyberattack. Unfortunately, that system is not back up and operating yet. Our Smilow Cancer Hospital clinical team is working closely with our ITS colleagues to build an internal, secure environment for an in-house operation of the Elekta software system.

In the interim, our Radiation Oncology team continues to evaluate the treatment needs for each of our patients. Although the Elekta cloud is not online, our team has developed a safe and secure method to treat our patients, which we are now implementing. About half of our patients currently on radiation oncology treatment are being treated today. We expect to be able to resume treatment for all patients by Tuesday. Radiation Oncology physicians and staff are communicating with each patient individually.

Referral of new patients who need radiation therapy should continue as usual. Smilow Radiation Oncology will continue to evaluate patients, perform simulations, create treatment plans, and begin therapy without delays.

Thank you for your continued partnership in the treatment and care of our patients. We will continue to keep you updated on this evolving situation. Please reach out to [Peter Glazer, MD, PhD](#), Chair of Therapeutic Radiology, [James Yu, MD, MHS](#), Associate Chief Medical Officer and Medical Director, Smilow Radiation Oncology, or [Lynn Wilson, MD, MPH, FASTRO](#), Executive Vice Chair and Director of Clinical Affairs for Therapeutic Radiology, with any questions about patient treatment or to discuss urgent clinical concerns.

### **Recent Voluntary Withdrawal of FDA Accelerated Approval of Specific Indications for Drugs**

Many breakthrough cancer therapies were approved by the FDA's accelerated approval program, which allows the drug's specific indication to be approved based on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit for a serious condition. The continued approval of the specific indication may be contingent upon verification of clinical benefit in confirmatory trial(s). The drug or its indication must be withdrawn if the confirmatory trial(s) fail to verify clinical benefit.

Recently, the indications for the following drugs with accelerated approval were voluntarily withdrawn by the manufacturer based on the result of confirmatory trials not meeting their primary endpoints.

- Durvalumab and atezolizumab were withdrawn as second-line therapy for bladder cancer
  - DANUBE trial for durvalumab failed to meet its primary endpoint of overall survival (OS)
  - IMvigor211 trial for atezolizumab failed to meet its primary endpoint of improved OS
  - Both drugs are no longer in NCCN Guidelines and ClinPath (Via) pathways
- Nivolumab and pembrolizumab were withdrawn as subsequent-line therapy for small cell lung cancer
  - CheckMate 451 and CheckMate 331 trials for nivolumab did not meet their primary endpoint of OS
  - KEYNOTE-604 trial for pembrolizumab failed to demonstrate a statistically significant increase in OS
  - Both drugs are still in NCCN Guidelines as category 3 recommendation, but are NOT in ClinPath pathways

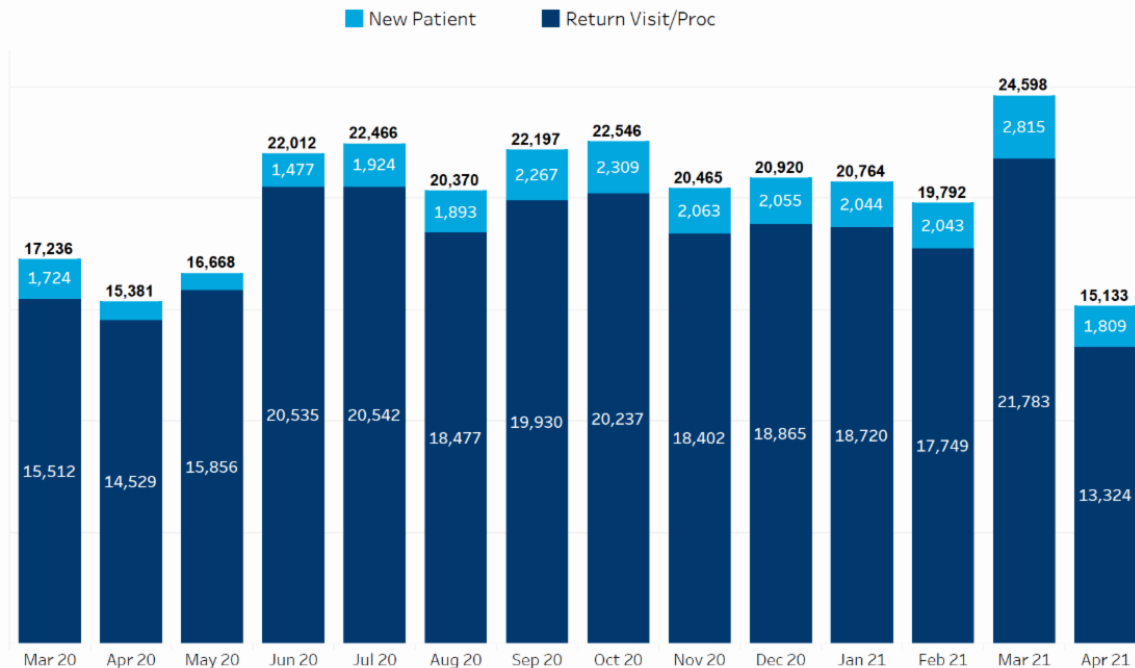
### Vaccinations

Yale New Haven Health now has ample open appointments across our geography. Please encourage your patients, colleagues, friends, and family to get vaccinated by scheduling through the [online portal](#).

### Patient Volume

Our patient volume has seen a 43% increase across the Smilow Cancer Hospital Network from March 2020 to March 2021. Thank you to all of our physicians, nurses, and staff for their dedicated efforts to care for and treat our patients.

**Visit Volume by Visit Type:** 43% Increase From March 2020 To March 2021  
March 1, 2020 - April 21, 2021



## Smilow Star!

We are proud to recognize **Barbara Holahan**, a Clinical Referral Specialist at the Smilow Cancer Hospital Care Center in Trumbull as a Smilow Star. Each day, Barbara provides personalized patient-centered care to all the new patients referred to the Breast Center in Trumbull. She is kind and empathetic on the phone. She gives each patient the time to ask questions and makes time to get to know them individually. The Care Center in Trumbull recently implemented Next Day Access and Barbara was instrumental in making this a success. She works hard to get our patients scheduled to see a provider the next day and if that is not possible she confirms availability for them within 5 days. Barbara has a wonderful relationship with staff from many areas of the health system. Her personal touch and her winning personality make anyone who is in contact with her feel special and that they have her undivided attention. Thank you, Barbara, for your daily commitment to our patients!



Best regards,

**Nita Ahuja, MD, MBA, FACS**

Interim Director, Yale Cancer Center  
Interim Physician-in-Chief, Smilow Cancer Hospital

**Lori C. Pickens, MHA**

Senior Vice President and Executive Director  
Smilow Cancer Hospital

**Kevin G. Billingsley, MD, MBA**

Chief Medical Officer  
Smilow Cancer Hospital

**Kim Slusser, MSN, RN, CHPN, NEA-BC**

Vice President for Patient Services  
Smilow Cancer Hospital

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