



Society for Immunotherapy of Cancer

July 25, 2017

The Honorable Mike Kelly
1707 Longworth House Office Building
Washington, D.C. 20515

The Honorable Ron Kind
1502 Longworth House Office Building
Washington, D.C. 20515

The Honorable Markwayne Mullin
1113 Longworth House Office Building
Washington, D.C. 20515

The Honorable Ami Bera
1431 Longworth House Office Building
Washington, D.C. 20515

Dear Congressmen Kelly, Kind, Mullin and Bera:

Thank you for forming the Health Care Innovation Caucus and for allowing the Society for Immunotherapy of Cancer (SITC) to submit comments on innovative policy ideas that can improve the quality of health care for all Americans. We believe the timing is excellent for launching this bipartisan effort, given the rapid progress that is taking place in biomedical research and the growing opportunities to deliver new advances to patients. With nearly 2,000 members representing 17 different medical specialties, SITC is the world's leading member-driven organization specifically dedicated to improving cancer patients' outcomes by advancing the science and application of cancer immunotherapy. SITC aims to further the application of immuno-oncology in first-line therapy, as a standard treatment for a broader range of patients, and to continue to develop biomarkers to better predict combination strategies and therapeutic response.

The field of immunotherapy is revolutionizing treatments for many forms of cancer. With more than 1,500 immuno-oncology drugs in development, immunotherapy treatments are poised for rapid growth. Immunotherapy offers patients with even late-stage cancers a meaningful hope for survival – and often a better quality of life than they would experience with traditional forms of treatment. Developing ways to more accurately measure the value of these new cancer agents has become a high priority for clinicians, patients, payers and regulatory bodies in the United States.

In addition to the raw cost of a treatment, there are other important factors to consider when determining the value of cancer immunotherapy. Unlike traditional therapies, many immunotherapies require only one treatment. Because immunotherapies use the patient's own immune system to fight their cancer, many patients experience very few or limited duration side effects. This allows many to continue working. And often they can drive themselves to and from appointments, meaning there is less disruption to the lives of their family members.

A great example of the progress we have made in the field of immunotherapy is the approval of two therapies that use a patient's own T-cells to attack their cancer. Known broadly as CAR-T, Chimeric Antigen Receptor T-cell therapy is relatively new to the field but is changing the face of cancer care. Currently, the Food and Drug Administration (FDA) permits CAR-T to be used only as a therapy of last resort; however, with one administration of the therapy, some patients, who would otherwise succumb to their disease, are *cured* of cancer.

The Centers for Medicare and Medicaid Services (CMS) included a proposal for reimbursing providers who administer CAR-T in their most recent hospital Inpatient Prospective Payment System (IPPS) rule. Ensuring hospitals are adequately reimbursed for these therapies will guarantee that Medicare patients have appropriate access to CAR-T. We have included a copy of our IPPS comment letter for your review.

While we were encouraged to see CMS include CAR-T reimbursement in the proposed rule, we do not believe the payment methodology proposed by CMS is the most appropriate one for CAR-T. Moreover, we believe that CAR-T is just the tip of the iceberg. We hope that through the proposed rule, CMS can establish a clear glidepath for setting the reimbursement rate for future developments in immunotherapy so that hospitals can deliver these lifesaving treatments to patients without wondering if they will be reimbursed fairly.

As CMS continues to transition away from traditional fee-for-service approaches, we believe establishing the appropriate factors to determine the value of cancer immunotherapy is imperative and falls squarely within the agency's mission. Decisions that CMS makes about how to determine the value of immunotherapy will have major implications for coverage and reimbursement. Having a clear and appropriate set of standards will help prevent unnecessary regulations and costs that would restrict access to these exciting new treatments.

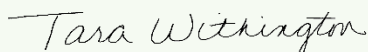
SITC is committed to collaboration with CMS, quality improvement organizations, and private payers in healthcare quality and assessment-related activities to make recommendations when input is needed, educate stakeholders and policy makers, and better articulate the value of cancer immunotherapy. We believe the Health Care Innovation Caucus can play a vital role in ensuring that CMS develops appropriate measures of value as it concerns cancer care. We would welcome the opportunity to work with the caucus on this important initiative.

As an example of our ongoing work in this area, SITC is proud to be the first and only organization dedicated to cancer immunotherapy to be accepted as a formal member of the Commission on Cancer (CoC), a program of the American College of Surgeons. The CoC is the nation's leading accreditation body for cancer care and has established a strong partnership approach to defining and measuring quality as it relates to managing patients with cancer. Today, more than 80 percent of Americans with cancer will seek treatment at a CoC-accredited facility. SITC is helping to establish and implement immunotherapy at CoC-accredited institutions and to develop mechanisms for collecting data and educating healthcare providers on the optimal way to deliver immunotherapy.

Again, thank you for the opportunity to share with you the promise of immunotherapy in cancer care and how these innovative therapies are changing cancer care for the better. We would welcome the opportunity to sit down with your staff to further discuss additional advancements in our field and some of the ideas we have for implementing value-based care measures in cancer care.

Thank you,

Sincerely,

A handwritten signature in cursive script that reads "Tara Withington".

Tara Withington, CAE,
Executive Director, Society for Immunotherapy of Cancer