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Smart Patients Get Smart Care™

Why Policy Matters – Understanding How Your CLL / SLL Journey is Affected

September 27, 2023

10:30 AM PT, 11:30 AM MT
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Speakers

Speaker
Saira Sultan
Director of Government Affairs & Public Policy
CLL Society

Moderator and Speaker
Brian Koffman, MDCM (retired), MS Ed
Executive Vice President and Chief Medical Officer
CLL Society

Welcome
Robyn Brumble, MSN, RN
Director of Scientific Affairs and Research
CLL Society

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Why Policy Matters – Understanding How Your CLL/SLL Journey is Affected

Dr. Brian Koffman MDCM (retired) MS Ed
Co-Founder, Executive VP, & Chief Medical Officer
CLL Society

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Discussion Outline

1. Explain what policy and advocacy (P&A) work is
2. Examine why CLL Society decided to engage in P&A
3. Review the structure and focus of CLL Society's P&A work
4. Give examples of recent P&A successes
5. Share a personal story of why P&A matters for CLL/SLL patients
6. Point out our present and Future P&A Challenges

CLL Society's Policy Institute is Focused on Three Key Pillars:

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Needs of the Immunocompromised

COVID-19 shed light on the need for CLL Society to regularly engage with government officials on behalf of our immunocompromised community. Our work on behalf of the estimated seven million immunocompromised Americans will not be over when the world transitions from the pandemic to the endemic phase.

Learn More

Access

Regulations that ensure access to adequate and affordable healthcare for all individuals living with CLL and SLL is of the utmost importance. We must also advocate to protect equitable and quality cancer care for every person, regardless of their demographic, socioeconomic status, or geographic location.

Learn More

Innovation

It is crucial to address legislative efforts that may potentially slow down the development of better medications to treat CLL and SLL. We must continually seek to improve processes and increase FDA engagement with patient advocacy organizations through their Oncology Center of Excellence.

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CLL Society's History of Advocating for the Immunocompromised

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We worked tirelessly to have government agencies change the definition of who is considered immunocompromised:

The NIH definition:

"This section pertains to people who are moderately or severely immunocompromised, which includes those who:

- Are receiving active treatment for solid tumors and hematologic malignancies.
- Have hematologic malignancies (e.g., **chronic lymphocytic leukemia**, non-Hodgkin lymphoma, multiple myeloma, acute leukemia) **and are known to have poor responses to COVID-19 vaccines or an increased risk of severe COVID-19, regardless of the treatment status for the hematologic malignancy."**

CLL Society's History of Advocating for the Immunocompromised (Continued)

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Special Considerations in People Who Are Immunocompromised:

- Vaccine response rates may be lower in patients who are moderately or severely immunocompromised. They would have a different vaccine schedule.
- Some people who are immunocompromised have prolonged, symptomatic COVID-19 with evidence of ongoing SARS-CoV-2 replication.
  - Longer and/or additional courses of ritonavir-boosted nirmatrelvir (Paxlovid)
  - Longer and/or additional courses of remdesivir
  - High-titer COVID-19 convalescent plasma from a vaccinated donor who recently recovered from COVID-19 likely caused by a SARS-CoV-2 variant similar to the variant causing the patient's illness

ODAC: Oncologic Drugs Advisory Committee

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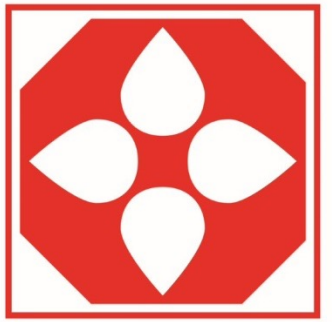
The purpose of the ODAC is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and make appropriate recommendations to the Commissioner of the FDA.

- ODAC wanted to remove a PI3K inhibitor used for CLL/SLL from the market
- PI3K Inhibitors approved for CLL/SLL
  - Duvelisib
  - Idelalisib
- CLL Society spoke at the ODAC meeting to advocate for keeping the drugs available for CLL/SLL patients
- Both are still available today

Some Components of the Inflation Reduction Act



Out of Pocket Cap

“Smoothing”

Direct Price Negotiation

PIRC
REBALANCE THE IRA

Coalition Started By CLL Society

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Home About Us Resources Join Us

Visit: https://rarecancerira.org

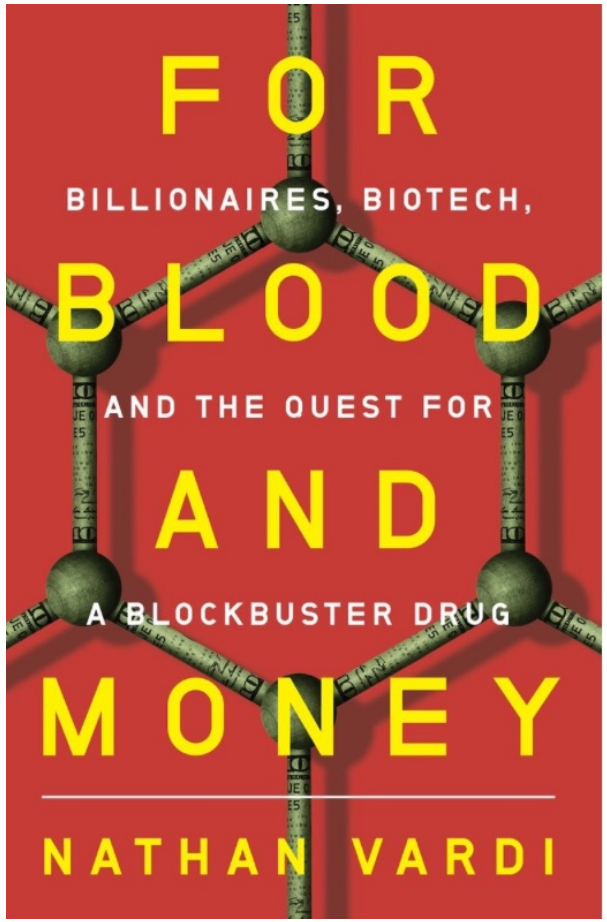
Protecting Innovation in Rare Cancers (PIRC) Coalition

Recognizing the need for a collective voice to represent the broader rare cancer community, PIRC will work tirelessly to safeguard access to innovative treatments for patients and families affected by rare cancers.

PIRC

PROTECTING INNOVATION IN RARE CANCER

I'm Still Alive Because of Innovation in CLL Therapy



My story:

- 2005: Diagnosed, many high-risk biomarkers
- 2008: Failed bone marrow transplant, 5% chance of 5-year survival
- 2011: Ran out of options

My personal best options were clinical trials:

1. PCI-32765: ibrutinib (Imbruvica), the first BTK inhibitor for CLL
2. JCAR-014: liso-cel (Breyanzi), likely the first CLL CAR-T
3. Epcoritamab: **BITE (Bi**specific **T** Cell **E**ngager) monoclonal antibody, first CLL patient in the US on the protocol

Other clinical trials:

- AZD-7442 (Evusheld PREP for COVID-19)

If not for the innovation of newly discovered therapies, I would have died many years ago.

How Innovation in CLL/SLL Therapies Has Helped Others

- Many patients who were out of options were saved by ibrutinib and newer BTKi's (acalabrutinib & zanubrutinib).
- Some patients need to be switched from ibrutinib to a different (newer) BTKi due to drug intolerance and have had many more years of remission as a result.
- Venetoclax offers a potent fixed-duration therapy option for frontline and relapsed/refractory CLL/SLL.
- Multiple patients have utilized PI3K inhibitors to either control their disease or serve as a bridge until they can receive other therapies, such as CAR-T.
- Pirtobrutinib is now being used with great success off-label to help "double refractory" patients who are low on options.

We Need More Options Not Fewer

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Our work isn't done!

- Once BTKi drugs and venetoclax fail, options are few with limited durability.
- New therapies are still desperately needed, and we need to ensure the pipeline stays open and active.

We still need options that are:

- Accessible (approved and covered by insurance)
- Affordable (regardless of insurance status)

This is some of what we are continually advocating for through CLL Society's Policy Institute!

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LEAD

FOLLOW

MONITOR

New Inflation Reduction Act ("I**RA**") **Law and Implementation**

Congress passed a law last year making some structural changes to the Medicare Part D and Medicare Advantage programs, and requiring direct government price negotiation in Medicare.

- Centers of Medicare and Medicaid Services (CMS) has created an entire division to implement the law.
- There are several 'pro' and 'con' implications for our community.
- We've spent significant time analyzing the implications for our community.
- We assessed which pillars of CLL Society's Policy Institute this falls under and what others are doing to support or oppose all the work underway in the government to ensure the details are implemented.

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PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Purpose

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- Speak loudly with one voice
- Speak from a rare cancer perspective
  - ***Educate*** *ourselves (& our communities)*
  - **Applaud** what we can
  - **Prepare** for what is coming
  - **Fight** against what must change
    - NOW AND NEXT YEAR
    - PREPARATION

We have the “benefit” of the President’s focus on cancer… let’s use that credibly and responsibly…

Some Components of the Inflation Reduction Act

Out of Pocket Cap

“Smoothing”

Direct Price Negotiation

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Out-of-Pocket Cap

- Beginning in 2025, Part D enrollees' out-of-pocket (OOP) costs will be capped at $2,000.
- Practically speaking, depending on one's Part D plan, currently patients pay:
  - a deductible of now more than $505/yr.,
  - then a cost-share or co-insurance amount per drug; for cancer patients, drugs often on 'specialty tier' – incurring 25-33% of the drug price in OOP costs
  - Finally, a catastrophic phase in which patients pay nothing

- About 20% of Medicare beneficiaries are expected to reach the $2,000 cap
- This amount will be indexed to rise at the rate of growth in per capita Part D costs.
- This cap does not apply to other parts of Medicare

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“Smoothing” or Medicare Prescription Payment Plan (MP3)/Implementation Recommendations

A new program allows patients to spread their OOP costs in both Medicare Part C and D across the plan year

Implementation and Communication Plans Underway

CLL Society Supports Program and is Advocating in Support of Details that Support Our Patients

- Option to opt-in/out right at the pharmacy counter should come sooner rather than later.
- What does the doctor have to provide to show ‘urgency’?
- Allow auto-renewal after first opt-in (w/ notice to patients to opt out ...like traditional Medicare)
- Is there a way to handle high costs hitting mid-year and not benefitting as much – e.g., any circumstances warranting rolling one year’s obligations into next year?
- Grace period of two months (vs 3 mos. in ACA);

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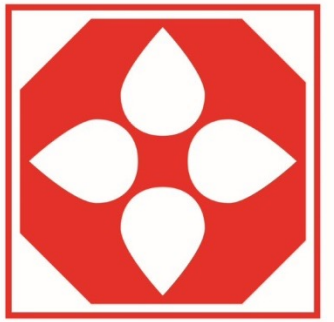
“Smoothing” Program Implementation Recommendations



- Clarify that even missing grace period doesn’t mean that if obligation is satisfied, you can’t re-enroll.
- Make appeals easier
- Can every plan be required to use uniform processes, forms, etc. Easily accessed on website? Standardized.
- Annual Plan reports – unusual drop out rates or other red flags should require immediate remedial action, must allow previous patients to appeal, etc.”
- Prohibit any contractual relationships between Plans and pharmacies – could force delays, require physician documentation re urgent claim opt-in, etc.
- “Likely to benefit” – ways to identify patients in helpful way vs. leave it to the plans (esp. given plans required to provide extra communication). Previous year’s spend threshold? Or certain diagnoses? Etc.
- Helpful or harmful for pharmacy to remind participants that payments are still due? (Patient will start paying at the POS again, and yet may have outstanding bills from the program)

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Direct Government Price Negotiation

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Sept 1 = "**First 10"** drugs for direct government price negotiation

Imbruvica – only cancer drug chosen for the first year of the program

Oct 2 – Comments due to CMS

Nov 6 – Imbruvica Listening Session (12:00-1:30pm ET)

Sept 1 '24 – Maximum Fair Prices (MFP) announced

Jan 1 '26 – MFPs go into effect

Why and How Policy Affects Our Community

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Questions?

This Program Was Made Possible Through Generous Donors Like You and Grant Support From

Thank You for Attending!

Please take a moment to complete our **post-event survey**, your feedback is important to us

If you're question was not answered, please feel free to email support@cllsociety.org

Join us on Monday, October 23rd for our next webinar, The CLL / SLL Medicine Cabinet: Understanding Your Available Treatment Options

CLL Society is invested in your long life. Please invest in the long life of the CLL Society by supporting our work

cllsociety.org/donate-to-cll-society/