VIA ELECTRONIC DELIVERY

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Brooks-LaSure:

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to submit feedback, including input from our patient communities, on the Centers for Medicare & Medicaid Services' (CMS') draft guidance for the Medicare Drug Price Negotiation Program (MDPNP) for initial price applicability year 2027 (the Draft Guidance).

PIRC is a collaborative, multi-stakeholder, patient advocacy coalition focused on improving access to and affordability of existing treatments while preserving the incentives required to advance future innovations in rare cancers. The coalition seeks to fulfill an important role in exchanging information and collaborating toward educating both our rare cancer communities and policymakers on the impact the Inflation Reduction Act (IRA) might have on access to existing Part D drugs and development of new therapeutic options.

As you are likely aware, cancer patients can face significant challenges in not only finding the best treatment option but being able to afford their prescribed treatments. Individuals fighting rare cancers typically have a limited set of effective therapeutic options and treatment affordability can be a matter of life and death. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with enabling Part D enrollees to opt into Medicare's new payment program and spread out-of-pocket costs over the plan year will greatly reduce the risk that Medicare's cancer patients must choose between paying for their medications and maintaining access to food and housing.

Given the typical cost of anti-cancer treatments and the impending cap on Part D out-of-pocket costs, any MDPNP savings on anti-cancer treatments will likely accrue to the Medicare program

rather than patients utilizing those treatments. While this may not be the result our patients anticipated from the IRA, it is consistent with Congress' expectation that MDPNP savings would offset the estimated $30 billion increase in Medicare spending due to Part D benefit redesign.[1]

Our comments are intended to aid CMS in ensuring that the MDPNP delivers on its promise of improving the health and lives of Medicare beneficiaries, including those with rare cancers. We believe that to achieve this goal, CMS must proactively consider downstream impacts of broad reaching initiatives like the MDPNP and mitigate any risk that an "unintended" consequence might erode benefits patients anticipate from the initiative. As more fully articulated below, PIRC and its member organizations:

- Appreciate that CMS seeks to refine its stakeholder engagement approach to enable more robust and meaningful patient participation.
- Urge CMS to reconsider its definition of qualified single source drug for negotiation eligibility purposes.
- Acknowledge that the contours of the orphan exemption are statutorily defined and urge CMS to use its available discretion and work with stakeholders, internal teams, and Congress to ensure that the MDPNP does not erode incentives for new rare disease approvals of existing treatments.
- Urge CMS to remove ambiguity and inconsistencies with respect to considering off-label uses of selected drugs as it prepares an initial offer.
- Recommend that CMS enforce Part D plan requirements to base utilization management tools on evidence and include all or substantially all products within protected classes on plan formularies.

PIRC appreciates that CMS seeks to refine its stakeholder engagement approach to enable more robust and meaningful patient participation.

Patient advocacy organizations often struggle to fully participate in the processes CMS uses to solicit feedback on proposed Agency action due to time constraints, lack of awareness of opportunities to contribute, and uncertainty on the information CMS seeks. The 30-day timelines for input on CMS' draft guidance and other MDPNP implementation documents for IPAY 2026 were too tight for patient organizations to digest the documents and respond in advance of the comment period. PIRC was, however, able to gather input from our patient communities on the model documents for the Medicare Prescription Payment Program (MPPP) and contribute meaningful feedback within the 60-day comment period. We appreciate that

[1] Congressional Budget Office. Estimated budgetary effects of Public Law 117-169, to provide for reconciliation pursuant to Title II of S. Con. Res. 14. Published 2022. https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

CMS has responded to feedback from stakeholders by extending the comment period for the Draft Guidance for IPAY 2027 to 60 days.
PIRC similarly appreciates that CMS intends to include enhanced opportunities for patients, patient advocacy organizations, and other stakeholders to contribute information on selected drugs within the negotiation process. We had several concerns with the "listening session" format for patient engagement during IPAY 2026, including that:

- The demographic of patients contributing during the listening sessions was not representative of the Medicare patient demographic.
    - People of color were substantially underrepresented.
    - Some contributors were outside the Medicare population and appeared to believe that the MDPNP would reduce out-of-pocket costs for all patients.

- The format was uncomfortable for patients. Participating patients shared very personal information on their experience with cancer and other serious, life-threatening conditions, and CMS staff remained silent other than to let the individual know that their time was up. The overall impression was one of cold detachment on CMS' part.

- The patient and patient advocacy community did not have a clear understanding of the information CMS sought or how that information would be used within the negotiation process.
    - Some participants believed that the negotiated price would apply beyond Medicare.
    - Most believed that the savings from negotiation on Imbruvica would be passed on to patients.
    - Many patients expressed a belief that Part D plans pay an inflated "sticker price" for drugs and remained unaware of the role of PBMs, rebates, and other price concessions currently in use to reduce net price to manufacturers.
    - Few participants in listening sessions were aware of the parallel paths of Part D redesign and IRA drug price negotiation.

- The lack of back-and-forth dialogue likely deprived CMS of information that might have been helpful toward CMS' understanding of the patient perspective on the selected drug and its therapeutic alternatives.

- Participation was likely hampered by CMS' use of the Federal Register to "get the word out."

PIRC fully supports CMS' stated intention to create additional opportunities for stakeholder engagement and to include formats that enable a meaningful dialogue among participants as well as between participants and CMS staff. We similarly urge CMS to:

- Work with patient advocacy organizations to ensure robust and meaningful participation from impacted patient communities. This might be particularly helpful when multiple selected drugs share an indication and/or are used to treat a particular condition.

    - Patient advocacy organizations are not only trusted messengers within their patient communities, but they have access to impacted patient populations that might ensure more representative participation.

- Clarify both the information CMS seeks and how it expects to use that information.

- Retain flexibility during the stakeholder engagement period of the negotiation process. For example, CMS could make MDPNP staff available for a dialogue organized by one or more patient advocacy organizations.

- Provide more advance notice of CMS-sponsored stakeholder engagement opportunities.

- Allow for submission of data and other information after the stakeholder engagement event.

Finally, while PIRC is pleased that CMS has responded to feedback from stakeholders and plans to respond to that feedback with improved engagement mechanisms, these changes in process will not have a meaningful impact on patients unless CMS also hears and responds to feedback on the more substantive aspects of its Draft Guidance for IPAY 2027. PIRC and its member organizations are particularly concerned that CMS has not mitigated the risk that Medicare cost savings from the MDPNP will come at a price for rare cancer patients and other individuals with significant unmet needs. These concerns are informed by our experience and understanding that new laws and policy initiatives can exert a considerable and increasing force on access to existing treatments and the development of new therapeutic options.

There is little doubt that the MDPNP will become an integral factor for investors and manufacturers calculating the feasibility of pursuing a particular drug candidate for a specific indication. Our patient communities fear that CMS' approach to implementing the MDPNP will inadvertently tip the scales away from innovation in cancers that lack a sufficient patient population to ensure relatively rapid return on investment and profit potential. We urge CMS to proactively consider approaches that achieve savings without disrupting or neutralizing the incentives for innovation that have driven scientific advances and fueled hope among rare cancer patients.

PIRC urges CMS to modify its definition of qualified single source drug (QSSD).

PIRC strongly urges CMS to reconsider its decision to identify a qualifying single source drug (QSSD) and its dosage forms and strengths, by referring to common active moiety (drugs) or common active ingredient (biologics). CMS' approach is not clearly mandated by the statutory language directing that the Agency include all doses, formulations, and dosage strengths of a particular drug as a single QSSD. The statutory language and the process for arriving at an initial offer, in fact, provides greater support for a QSSD definition based on NDA or BLA. For example, the determination of negotiation eligibility turns on how much time has elapsed since approval of an NDA/BLA yet CMS' definition would include NDA/BLA approvals that have not met the negotiation eligibility requirements. If Congress had intended that CMS include all ***indications*** **approved with a common active moiety/active ingredient**, it could easily have included those terms in the statute.

Similarly, the process of examining therapeutic alternatives to a selected drug in determining an initial offer could be rendered virtually meaningless if divergent conditions with variable 30-day supplies and diverse sets of therapeutic alternatives are somehow aggregated. The resulting calculation could easily fail to capture the cost of therapeutic alternatives for ***all*** uses of the selected drug. The biologic denosumab provides a good example of the potential unintended consequences of CMS' active moiety/active ingredient approach and its avoidable unintended consequences for rare cancers and other rare conditions. Denosumab is FDA approved as Prolia for post-menopausal osteoporosis and administered as 60 mg subcutaneous injection every 6 months. It is also approved as Xgeva for bone metastasis, multiple myeloma (approximately 37,000 cases per year) and in giant cell tumors of the bone (an extremely rare (1 in 1,000,000) predominantly noncancerous condition that destroys the bone). The recommended dose of XGEVA is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm with additional 120 mg doses on days 8 and 15 of treatment of the first month of therapy.

CMS may be able to avoid having to calculate a single price for denosumab if progress on marketing a biosimilar is sufficient to exempt it from selection, but this type of problem is certainly not unique to denusomab. CMS' definition of QSSD creates problems that make it all but impossible to utilize the statutory process and arrive at any initial offer that reflects use in any indication due to differential dosing and extremely divergent therapeutic alternatives.

In addition, our patient communities have significant concerns that CMS' QSSD definition will make new FDA rare cancer approvals for existing drugs unattractive from a financial perspective. A recent article[2] authored by scientists at the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center. The authors note that:

[2] Chambers JD, Clifford KA, Enright DE, Neumann PJ. Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act. JAMA Netw Open. 2023 Aug 1;6(8):e2329006. doi: 10.1001/jamanetworkopen.2023.29006. PMID: 37581890; PMCID: PMC10427936.

> Efforts to address prescription drug costs must balance the benefits of lower drug prices with downsides in terms of reduced future innovation. We provide new data to help understand the potential consequences of incentives inherent in the IRA for drug companies to curtail efforts to pursue future follow-on indications for orphan drugs. FDA approved roughly one quarter of orphan drugs from 2003 to 2022 for at least 1 follow-on indication, and the agency considered the majority of these indications in expedited review programs.
>
> How much the IRA will affect future innovation is unknown and a source of controversy. . .. The law may lead pharmaceutical manufacturers to develop more single-indication orphan drugs (which are not subject to negotiations) rather than follow-on indications. Our analysis suggests that the potential foregone follow-on indication approvals for serious illness and unmet needs could be nontrivial. Such potential losses should be considered against the gains to consumers and society that come with lower drug prices.[3]

For the initial year of the Medicare Drug Price Negotiation Program (MDPNP), Imbruvica® was the only cancer treatment selected for negotiation. Imbruvica® is a Bruton's tyrosine kinase (BTK) inhibitor that initially received accelerated approval in 2013 for the treatment of mantle cell lymphoma (MCL, voluntarily withdrawn in 2023) in patients who had received at least one prior therapy. It was subsequently approved for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) with 17p deletion, Waldenström's macroglobulinemia (WM), (a rare form of non-Hodgkin lymphoma), marginal zone lymphoma (MZL, voluntarily withdrawn in 2023), and chronic graft versus host disease (cGVHD) after failure of one or more treatments. The indication with the highest impact to the Medicare program is chronic lymphocytic leukemia (CLL), which is a chronic blood cancer of a type of white blood cell called the B-lymphocyte. CLL is the most common leukemia in adults in the United States, and is also classified as a type of non-Hodgkin's Lymphoma (NHL).

Imbruvica was the first Brutons Tyrosine Kinase (BTK) inhibitor and first oral treatment option for chronic lymphocytic leukemia and small cell lymphoma (CLL/SLL). Targeted therapies such as BTK inhibitors and the BCL2 inhibitor known as venetoclax have offered substantial efficacy against CLL/SLL and have transformed care for patients.

Although most CLL/SLL patients can expect a response to initial therapy, nearly all current treatment options are palliative and not curative. Most patients will experience one or more relapses during the course of their disease, and many are forced to either change treatments, take a "drug holiday," or adjust dosing due to drug intolerance. For patients with relapsed or refractory disease (or treatment intolerance), treatment decisions are highly individualized based on prior therapies, prior response, the reason for discontinuation of previous therapy, comorbidities, biomarker characteristics, patient preference, and therapeutic goals. Patients

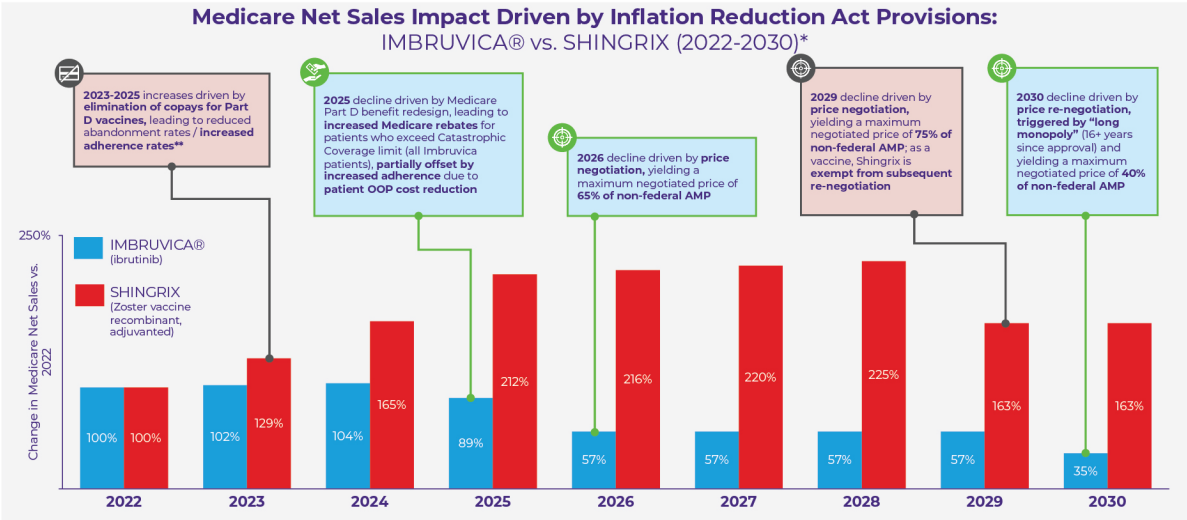
[3] Id.

can experience serial relapses and may be treated with all available agents at some point during their disease course.

The unfortunate reality is that despite significant progress in treating CLL/SLL, it remains an incurable cancer. Patients progressing after both BTK and BCL2 inhibitors face a poor prognosis with few treatment options other than PI3K inhibitors. There is, therefore, a significant unmet need for CLL/SLL patients. The primarily Medicare-age demographic for CLL/SLL, however, could exert pressures on manufacturers to steer away from product candidates, particularly small molecules given the shorter timeframe for negotiation eligibility and high likelihood that the patient demographic could drive disproportionately high costs to the Medicare program.

Rare cancer patients have serious concerns that CMS' negotiated prices will act as a signal deterring innovators from studying new treatment classes due to the combined risks of diminished market share from new in-class competitors and aggressive price negotiation through the MDPNP. An analysis comparing the MDPNP impact on Shingrix and Imbruvica illustrates the risk investors and manufacturers will assume if they develop new treatments or new uses of existing treatments in rare cancers that, like CLL/SLL have a significant Medicare population.[4] We strongly urge CMS to recognize the inherent uncertainties the MDPNP presents for innovation and access in rare cancers and that it diverge from the ceiling price only when there is a strong justification for doing so and no unmet treatment needs in the impacted disease state(s).

A Tale of Two Drugs: How the Inflation Reduction Act of 2022 Impacts Pharmaceutical Classes Differently



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*Directional estimate only based on publicly available data; Excludes impact of any market changes not driven by the IRA (e.g., disease epidemiology, product preference share, indication expansion, etc.); Assumes 2% price increases that do not trigger inflation penalties; **Assumes Shingrix adherence rates rise from 34.5% to 69.0% based on 65+ pneumococcal vaccination rates as an analog; Source: Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Lu et al, *Surveillance of Vaccination Coverage Among Adult Populations* (2018); Putnam Medicare Price Negotiation Database 2022; Putnam Analysis 2022

[4] The Inflation Reduction Act: A tale of two drugs - Putnam (putassoc.com)

Over an eight-year period, revenue from Medicare sales of Imbruvica are anticipated to decline by 65%. It is generally anticipated that each of the newer BTK inhibitors will be selected in the first year of negotiation eligibility and experience similar revenue losses. This financial picture is not only likely to deter some investors from developing products in CLL/SLL but to deter investment in research such as combination therapy protocols that could lead to improved patient survival. The narrow orphan exemption (discussed below) combined with CMS' intention to refer to a product's first NDA/BLA in determining selection eligibility likely exacerbate the financial downside of product development in this cancer.

PIRC is also concerned that CMS' implementation strategy and QSSD definition create the potential that the Primary Manufacturer/Secondary Manufacturer construct will drive a substantial set of burdens on Primary Manufacturers that were not envisioned when the IRA was enacted. Under this construct, the NDA/BLA holder is the Primary Manufacturer even if a Secondary Manufacturer holds exclusive commercialization rights on a separate indication approved under a separate NDA/BLA. The Secondary Manufacturer has no IRA-related obligations, yet its activities or omissions could place the primary manufacturer in legal jeopardy in the form of substantial fines and penalties. Manufacturers could not have foreseen the new landscape CMS' definition of a qualifying single source drug has created, and there may be no recourse available to Primary Manufacturers under the contractual relationship between the parties. We urge CMS to reconsider its definition of QSSD.

PIRC urges CMS to use its available discretion in implementing the Orphan Drug Exclusion and work with stakeholders, internal teams, and Congress to ensure that the MDPNP does not erode incentives for new rare disease approvals of existing treatments.

Last year, CMS solicited stakeholder feedback on ideas for implementing the Orphan Drug Exclusion that preserve incentives facilitating orphan drug development. We were disappointed that CMS' Draft Guidance for IPAY 2027 reinforces the narrowest interpretation of the statutory exclusion.

The sets of incentives encouraging the development of treatments for small-population diseases have generally worked well to expand treatment options and improve survival for patients with CLL/SLL and other blood cancers. The IRA's narrow exclusion for orphan drugs, however, creates a landscape in which multiple designations for a promising therapy will negate eligibility for the exclusion, thereby substantially complicating analyses on the potential for favorable return on investment which, in turn, may delay or reduce development of potentially effective and life-saving treatments for patients. Manufacturers may face pressures to focus on an orphan indication with the largest patient population rather than the disease state that is most suitable for clinical trials. This could impact the time it takes to move a product from bench to market, increase costs associated with securing a first approval, and deter studies leading to FDA approvals in cancers with extremely small patient populations.

We do not believe Congress or the Administration sought to limit research and development in orphan diseases generally or in rare cancers. Manufacturers secured orphan designations well before the IRA was enacted and could not have considered that a relatively narrow designation would later drive consequences to research and development in other indications. PIRC is concerned that as the drug price negotiation program becomes a tangible reality for manufacturers and investors, it will drive decisions on the drug candidates and/or indications manufacturers and investors are willing to pursue.

We believe researchers, investors, and manufacturers should be rewarded, not penalized, for investing in research and development to secure FDA approval for new indications (rather than relying on off-label use). It would be a tremendous tragedy if Congress' efforts to improve healthcare affordability created an environment in which future treatments would never be indicated for use in rare cancers despite their potential to transform patient care. PIRC also expects that our concerns could be greatly mitigated if CMS reconsidered its QSSD definition. This is particularly true within the context of the impact that loss of Orphan Drug Exclusion status would have on the date of selection eligibility. CMS stated:

> In the event that a drug or biological product loses Orphan Drug Exclusion status, pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval of the drug or licensure of the biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation

Finally, PIRC urges CMS support for Congressional action to broaden the orphan exclusion to align with public policy favoring development of new and existing orphan treatments to address unmet needs in rare diseases. The statutory language as it stands leaves manufacturers with a lose/lose proposition and jeopardizes patient access to promising therapies. Moreover, it is unlikely to benefit the Medicare program or society as a whole.

PIRC urges CMS to remove ambiguity and inconsistencies with respect to considering off-label uses of selected drugs as it prepares an initial offer.

Section 60.3.1 "Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication" provides that:

> For initial price applicability year 2027, for the purpose of identifying indications for the selected drug, CMS will identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. ***CMS may consider off-label use*** when identifying indications if such use is included in nationally recognized, evidence-based guidelines and listed in CMS recognized Part D compendia. (emphasis added)

Although PIRC and its member organizations strongly believe that FDA approval is the best way to ensure that **all** patients have equitable access to the best treatment options for their particular cancer, off-label use remains an important part of cancer care. We are concerned that CMS' use of the term "may" conveys an intent to determine the set of uses for a selected drug on a case-by-case basis. This ambiguous standard creates an additional layer of uncertainty to an already-uncertain process. We urge CMS to either provide an explanation for excluding off-label uses or include those uses in its decision processes.
PIRC recommends that CMS enforce Part D plan requirements to base utilization management tools on evidence and include all or substantially all products within protected classes on plan formularies.

PIRC appreciates that the MDPNP is one part of a broader set of changes to the Part D program and that CMS "does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 are warranted." We are, however, concerned that patients could face immediate and potential harmful access constrictions as Part D redesign changes converge with implementation of negotiated prices for selected drugs.

Our concerns appear to be valid in light of a 2023 double-blind, web-based survey distributed through Cencora's Managed Care Network to pharmacy directors, medical directors, and contracting managers/directors. This survey and its analysis provide insight into how managed care entities perceive and will likely react to the IRA drug provisions[5]. We are especially concerned that most respondents expect that the IRA's Part D changes will lead to narrower formularies in comparison to pre-IRA formulary design.

In addition, most payers are acutely aware of the increased liability for Part D plans and expect:

- greater use of utilization management tools
    - 42% anticipated greater utilization management overall.
    - 32% expect greater utilization management for high-cost medications.
    - 10% (n = 5) anticipate no change
- Increased Part D plan premiums
    - 8% anticipate a premium increase greater than 10%.
    - 40% expect an increase from 5% to 10%.
    - 18% anticipate an increase up to 5%.
    - 12% believe Part D plan premiums will remain at their current levels.
    - No payers expect that premiums will be lower than current levels.

As negotiated drug prices are implemented, plans will face downstream impacts to their bottom line as the traditional rebates (reflected after the point of sale) are replaced by the MFP

[5] Ford C, Westrich K, Buelt L, Loo V. Payer reactions to the implementation of the Inflation Reduction Act: forecasting future changes to Medicare Part D plans. Presented at: AMCP Nexus 2023; October 16-October 19, 2023; Orlando.

(reflecting discounted cost at the point of sale). The dynamics are uncertain and will likely vary based on whether there are other available drugs within the same category and class as the selected drug, as well as the PBM's and/or plan's ability to contract with manufacturers for favorable rebates on non-selected drugs.

PIRC is concerned that simply "monitoring" plan activities will not sufficiently protect Medicare beneficiaries. Without CMS intervention and/or oversight, it is likely that plans will determine which drug(s) are associated with the lowest financial liability and steer patients toward that drug through formulary inclusion/exclusion and tier placement. A selected drug might be the only available alternative for beneficiaries despite competing products that may offer improved effectiveness and/or greater tolerability.

As the first anti-cancer treatment for which a negotiated price will be implemented, Imbruvica serves as a good example of how the MDPNP and Part D redesign could impact patient access to prescribed treatments. According to NCCN Guidelines, the most appropriate frontline treatment for CLL and SLL depends on patient-specific factors, including characteristics of the cancer and mutation status, age, and comorbidities. Subsequent lines of therapy are chosen based on the previous treatment as well as the factors outlined above. BTK inhibitors offer considerable improvements in care for patients but can result in drug intolerance requiring interruption, dose reduction, and even treatment discontinuation. Although clinical guidelines and recommendations recognize that newer BTK inhibitors have greater tolerability that would tend to improve outcomes, there is still much to learn about the various BTK inhibitors through real world data generated over time. BTK inhibitors are also increasingly being studied in combination with other treatment options, and these uses should also be covered by Part D plans when the patient and their clinician determine that it is the best treatment option.

It is, therefore, vital that Part D plans, including MA-PD plans, include all available treatment options on their formularies, without imposing step therapy protocols, so that clinicians and patients are able to make treatment decisions based on what will enable the patient to achieve a durable treatment response while maintaining their quality of life. There is substantial concern that if Imbruvica is priced in a way that encourages health plans to insist on it as a first step, more patients will be steered away from care reflecting NCCN guidelines. Moreover, failure on one BTK inhibitor likely precludes use of other BTK inhibitors – making step therapy particularly inappropriate and potentially dangerous for patients given the limited lines of treatment available. At the same time, patients need to have access to all viable treatment options and those using Imbruvica successfully for their cancer are unable to take an alternative BTK inhibitor that may be more financially advantageous to a plan due to rebates and other price concessions.

We urge CMS to:

- Increase its oversight to ensure that plan formularies include all necessary medications and that expedited formulary exception processes enable access when patients need treatments not included on formulary.
- Provide Part D plans with clear guidelines on coverage, formulary tiers and utilization management (UM) tools, including enforcement of requirements that formulary process be transparent and utilization management strategies be based on clinical evidence.
- Proactively monitor the impact of the Manufacturer Discount Program, the MDPNP, and Part D redesign on formulary decisions and UM practices.
- Identify and mitigate in a defined timely manner any access constrictions, on the plan and sponsor levels as well as program wide.
- Establish a formal mechanism for patients and patient advocacy organizations to communicate their experiences, including any barriers to getting their prescribed medications when they need them, directly with CMS. We urge the Agency to create a dedicated communication channel as well as a set of proactive forums for patients and clinicians.

We are also gravely concerned that the protections that have been codified since 2006 for Part D drugs within the six "protected" classes, i.e., immune-suppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics, have eroded from one year to the next. CMS' rationale for designating these classes of drugs as requiring plans to include all or substantially all drugs within the class was designed to ensure that formulary designs do not disadvantage and discriminate against the vulnerable patients requiring access to specific drugs or combinations of drugs. That rationale is as valid today as it was when the protected classes were created.

Conclusion

PIRC appreciates the opportunity to contribute the perspectives of those within the rare cancer patient and caregiver community as CMS implements the drug price negotiation provisions of the IRA. We look forward to a continuing dialogue throughout the IRA implementation process and welcome the opportunity to discuss our comments or the experience of rare cancer patients generally.

Bag It Cancer
Biomarker Collaborative
CancerCare
Cancer Support Community
Chondrosarcoma Foundation
CLL Society
Cutaneous Lymphoma Foundation
Desmoid Tumor Research Foundation
Exon 20 Group
Hairy Cell Leukemia Foundation

ICAN, International Cancer Advocacy Network
MET Crusaders
No Stomach for Cancer
Ovarian Cancer Research Alliance (OCRA)
PD-L1 Amplifieds
The Healing NET Foundation
The National Pancreas Foundation