PERSONALIZED MEDICINE COALITION

October 18, 2019

ATTN: Steven D. Pearson, M.D., M.Sc.
Founder and President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

By electronic delivery

Re: Proposed Updates to the 2020 Value Assessment Framework Methods and Procedures

Dear Dr. Pearson:

The Personalized Medicine Coalition (PMC) appreciates the opportunity to submit comments regarding the proposed updates to the Institute for Clinical and Economic Review (ICER)'s 2020 value assessment framework methods and procedures, to be finalized in December of 2019.

Comprised of over 200 member institutions from every sector of the health care ecosystem, PMC, an educational and advocacy organization representing patients, providers, payers, innovators, and scientists from around the world, promotes the understanding and adoption of personalized medicine concepts, services, and products to benefit patients and the health system.

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, that help determine which medical treatments and procedures will work best for each patient. By combining this information with an individual's medical records, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

PMC's comments on the updates to ICER's value assessment framework, herein called the framework, are focused exclusively on the extent to which the proposed changes reflect a consideration of the value of personalized medicine products, services, and concepts. Considerations related to personalized medicine can significantly impact the assessment of comparative clinical effectiveness and comparative value. Treatment strategies that are targeted based on a patient's molecular characteristics and individual circumstances improve outcomes by allowing physicians to know which treatments may be more effective and safer to use for each patient. Doing so may in turn bring down costs by helping to avoid ineffective or harmful treatment options and reducing the downstream expenses associated with rapid disease progression and/or adverse events.

PMC welcomed the opportunity to provide broad comments to ICER regarding the 2020 framework on June 10, 2019. As reflected in our earlier comments, the framework would benefit from a greater consideration of personalized medicine within its objectives, methods and procedures.

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

To this end, PMC recommends that ICER recognize five principles related to personalized medicine as it considers the updated framework. These principles represent the foundation on which our general comments and our comments regarding specific proposed updates are based.

1. Considerations related to personalized medicine, such as heterogeneity of treatment effect, treatment efficiency (i.e., potential cost savings by avoiding less effective treatment or adverse side effects), and individual values and circumstances can significantly impact comparative clinical effectiveness and value assessment.

2. Diagnostic testing must be considered an integral part of the assessment of the value of treatment options where heterogeneity of treatment effect can be assessed, or efficacy and/or safety information can be obtained.

3. Methods for assessing value must consider real-world evidence (RWE) that can provide insights on emerging or evolving value elements over time.

4. Valuation approaches should be transparent and consistent; should include a broad array of benefits that are important to patients and society; and should adequately account for population diversity through consideration of patient heterogeneity.

5. All stakeholders must be engaged, and multiple perspectives must be integrated throughout the value assessment process.

A Statement on the Intended Purpose of This Letter

Many of PMC's members will present their own responses to ICER and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed updates to the value assessment framework methods and procedures.

General Comments Regarding the Framework

As we stated on June 10, 2019, in our comments on broad changes needed to the framework, we offer these general comments about how the scope of the framework may affect the field of personalized medicine. The next iteration of the framework will impact ICER evidence reports for all assessments initiated in 2020 and beyond. Personalized medicine considerations will affect many, if not all, of ICER's value assessments going forward, as evidenced by the fact that over the last four years (2015 – 2018), personalized medicines have accounted for more that 25 percent of all new drug approvals, and the number of newly approved personalized medicines is expected to continue to grow (Personalized Medicine Coalition, *Personalized Medicine at FDA: A Progress and Outlook Report*: http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_A_Progress_and_Outlook_Report.pdf).

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

The Population Perspective and Heterogeneity

The framework is intended to inform medical policies through a population-level perspective. ICER should not conflate, however, the impact of a therapy on patient health outcomes with the potential budget impact to any individual stakeholder or stakeholder group. We acknowledge ICER's statement that stakeholders focused on population-level decision-making, including payers and policymakers, are the intended audience of its value assessments. This does not discount or diminish, however, the negative consequences these assessments may have on patient access. A population-level framework may encourage the restriction of access to a new drug based on reported averages, which limits treatment options available to individual patients who may have benefitted from them.

Furthermore, by focusing on evaluating the overall average effectiveness, the framework doesn't encourage the generation of useful evidence on heterogeneity that can inform differential decisions about the extent to which individuals or subgroups may benefit from new health care technologies.

In ICER's published assessments, heterogeneity has not been featured strongly in the reports of the main clinical results, and in cost-effectiveness analyses heterogeneity has only been addressed post-hoc after the main model has been built. ICER's Evidence Rating Matrix does not focus on understanding heterogeneity or report results by subgroup. It is imperative that ICER recognizes the importance of evidence on heterogeneity, as it has been well established that reporting of differential value assessment across subgroups will lead to substantial health gains, both through treatment selection and coverage (Basu A. Estimating person-centered treatment (Pet) effects using instrumental variables: an application to evaluating prostate cancer treatments. *Journal of Applied Econometrics*. 2014 Jun;29(4):671-91; Espinoza MA, Manca A, Claxton K, Sculpher MJ. The value of heterogeneity for cost-effectiveness subgroup analysis: conceptual framework and application. *Medical Decision Making*. 2014 Nov;34(8):951-64; Kreif N, Grieve R, Radice R, Sadique Z, Ramsahai R, Sekhon JS. Methods for estimating subgroup effects in cost-effectiveness analyses that use observational data. *Medical Decision Making*. 2012 Nov;32(6):750-63).

ICER should consider, for example, how assessing the value of different therapies to individual patients could facilitate improvements and efficiencies at the population level by ensuring that only those patients who are most likely to benefit from new therapies actually receive them. The final decision of which therapy, or combination of therapies, is most appropriate for a patient must (1) be left to the patient working with his or her provider; (2) involve consideration of the patient's clinical circumstances and preferences; and (3) involve consideration of a therapy's long-term impact on a patient. Utilizing personalized medicine strategies, providers are able to identify individuals within larger populations that are more or less likely to respond to certain therapies. Therefore, inclusion of these considerations should, on balance, lead to population-level efficacy, safety, and efficiency.

Appropriate Consideration of Diagnostic Tests

The framework does not have a formal, consistent approach for the consideration of diagnostics intended to help guide treatment decisions where appropriate. The framework considers "evaluation of diagnostic tests and delivery system interventions by taking into account their unique nature or circumstances," but the framework does not specifically call on assessments to consider the validation, utility, and economic impact of diagnostic tests. Guidelines for a consistent approach should consider (1) when diagnostics should/should not be included

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

in assessment processes; (2) how (methodologically) diagnostics are included in the evidence review and economic evaluations; and (3) implications and standards for analyzing and reporting on patient subgroups. Diagnostic testing in personalized medicine is a key step on the path to getting the right medicine to a patient as early as possible. It is imperative that the framework considers testing an integral part of clinical decision-making by which efficacy and safety information of treatments can be obtained. The detection or measurement of biomarkers plays an important role in determining value across numerous clinical scenarios, many of which are subject to rapidly advancing scientific knowledge. The context of biomarkers within clinical scenarios must therefore be figured into the framework's methodology. Failure to explicitly address this important component of value at this time will undermine the usefulness and applicability of the framework going forward.

Value Factors

We recommend that the framework examine a broad range of factors specific to each evidence review within the appropriate context to inform and support determination of high-value care. This may include short-term affordability and long-term value, but these factors alone are insufficient. Furthermore, the valuation of sustainable access to high-value care falls short of a complete societal perspective of value (Sanders GD, Neumann PJ, Basu A, Brock DW, Feeny D, Krahn M, Kuntz KM, Meltzer DO, Owens DK, Prosser LA, Salomon JA. Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine. *JAMA*. 2016 Sep 13;316(10):1093-103). The societal perspective may often incorporate factors such as productivity and caregiver burden. A societal perspective will also ensure that all patient- and societal-focused benefits are included, not just those that will be accrued by the payer. Elements such as systemic efficiency (i.e., getting the most effective treatment to a patient, but also avoiding the use of treatments that will not work in some patients), the contribution of innovation to the further advancement of medicine, and the contribution of an innovation to an evolving care paradigm should be taken into consideration.

Alternative Value Assessment Framework Considerations for Rare Diseases

Not all conditions for which the value of treatments may be assessed are subject to the same set of weighted value factors. For example, standard assessment processes frequently fail to account for the unique characteristics of innovative therapies for rare diseases. Collecting clinical data in patient populations with rare diseases is challenging for many reasons, including: a limited knowledge of disease history and its progression; the fact that many of these conditions frequently affect particularly vulnerable groups such as children and are not associated with any established therapies; and the complications associated with trial results that are frequently associated with much greater uncertainty due to small numbers of patients. Rare disease treatments are further disadvantaged because standard value assessment methodologies are typically designed for more prevalent conditions with relatively lower incremental costs. PMC recommends that ICER develop alternative value assessment framework strategies for differing types of conditions such as rare and ultra-rare conditions that take into account the unique characteristics of these situations and their value to society. For example, ICER could take advantage of observational data, such as that coming from RWE sources like EHRs, registries, and natural history studies in the evaluation of treatments for rare diseases. However, until such time as alternative value assessment strategies can be put in place following solicitation of stakeholder comments, PMC recommends that ICER hold off on value assessments for innovative treatments for rare and ultra-rare conditions.

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

Length of Time for Review

While we appreciate that the timelines for responding to proposed process updates have been increased, they are often still insufficient for the purpose of soliciting feedback from multi-stakeholder coalitions like PMC. PMC and its members can support ICER by providing in-depth, technical insights on the subject matter of ICER's evaluations. But as a coalition, any insights we offer must represent the interests of a range of disciplines and balance the perspectives and needs of our many members, and it is impractical to be able to fully react to and respond to ICER's complex and lengthy reports in a short period of time. PMC also reiterates its recommendation that all comments submitted to ICER should be publicly available. ICER should give its rationale for issues that it has chosen not to incorporate or address. Longer timelines for ICER's review and consideration of stakeholder input and unlimited length requirements related to stakeholder feedback will allow for greater community acceptance of ICER's assessments.

Report Development and Stakeholder Engagement

PMC commends ICER on efforts to further engage stakeholders on policy development, both in recent value assessment reports and in the proposed revisions to the framework. Consideration of perspectives of all personalized medicine community stakeholders, especially patients and caregivers, is critical to getting the right treatment to each patient as early in their care as possible. However, we respectfully note room for greater engagement that can more completely integrate patients and other critical stakeholders into the value assessment process. In order to truly encompass and reflect clinical real-world experience and value to patients, these stakeholders' perspectives must be integrated throughout the process.

To encourage continued high-quality input, PMC recommends that ICER make the process for communication with patients and caregivers clear. We are pleased that ICER increasingly provides opportunities for patients to engage throughout a value assessment and to submit data. To complement ICER's *Patient Open Input Questionnaire,* ICER should emphasize and detail the patient-provided information that would be valuable for patient groups to collect. In addition, we recommend that ICER further expand the questionnaire to explicitly include separate questions for "each value element" prioritized by patients, caregivers, and providers during ICER's engagements on topics. Patient groups will be better able to accommodate requests and provide high-quality data the sooner they are made aware of a call for feedback and of what types of input/data collection will be useful.

Comments Regarding Specific Areas for Which ICER is Requesting Input

We appreciate ICER's call for comments on proposed updates to the framework and efforts through prior framework revisions that have provided greater alignment with personalized medicine practices and principles; however, further revision and refinement of the framework in this area is warranted to ensure the applicability and usefulness over the period during which the updated methodology will be implemented. Key recommendations related to ICER's specific requests for input are highlighted below.

1. *Augmenting efforts to use real-world evidence.*

We appreciate the steps ICER has taken to open the framework to the inclusion of a broader range of data sources for assessments, extending beyond randomized clinical trials (RCTs) to include, for example, RWE. RCTs have great value in determining the clinical safety and efficacy of therapies in optimal settings, but value

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

can differ in clinical settings due to variation in physician practices. RCT data is often very homogenous due to inclusion/exclusion criteria of trial participants; however, value assessments are meant to draw conclusions for the wider population. RWE, by contrast, provides evidence that is more relevant to a diverse population and can reveal when there are advantages for particular sets of patients. Furthermore, conducting RCTs for some personalized medicines is not feasible because it would be impossible to develop a large enough cohort of patients with a rare genetic variant necessary to demonstrate clinical significance. In these cases, RWE is instrumental to assessing the value of personalized medicine strategies. The proposed updates to the 2020 framework, including a process for formal request of stakeholders who are engaging on a review project to submit relevant RWE, and the exploration of opportunities with third party organizations to provide RWE, do not go far enough. It is unclear how these data will be incorporated into ICER evaluations, models, and value metrics, but it is important that RWE carry an appropriate amount of weight in evaluations and that this is defined *a priori* in the framework. RWE can also provide insight into "current" treatment patterns and standards of care, given that trials are typically conducted a number of years before a product's launch and the appropriate comparator may have changed since that time. Finally, RWE can also provide information on how patients who may often be excluded from RCTs due to co-morbidities or other criteria may benefit from a therapeutic in routine clinical practice.

The Food and Drug Administration is exploring the use of RWE in efficacy determinations and has a long history of its use in post-market surveillance processes. While ICER should continue to adapt methods for the routine use of RWE in evaluation processes, in these cases, any RWE generated for FDA review should be taken into consideration in ICER evaluations. In addition, it is worth noting that RWE is being used by international and European health technology assessment bodies as an alternative source of comparative evidence when RCTs are not feasible, or when evidence from RCTs is inadequate.

As part of the proposed updates, it is stated that ICER will explore collaborative relationships with organizations that may serve as sources of real-world data (RWD). There are risks associated with using third party organizations to generate and report RWD for use in value assessments, including potential bias and non-disclosed incentives to generate inefficient data. ICER should develop safeguards against these potential risks. Furthermore, RCT data is subject to quality standards, including "fit for use", which is needed to assure quality evidence for evaluation purposes. RWE should have a similar set of standards to assure quality and applicability of this data type.

Furthermore, through this process, ICER has proposed that it generate RWD to complement published data sources during its value assessments. Given the timing of ICER's assessments, it is unlikely that ICER or real-world studies developed by third parties would be afforded the rigors of scientific peer-review prior to inclusion as inputs in ICER's assessments. We therefore encourage ICER to thoughtfully consider methodologic and process guidelines for RWE developed by the Joint International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the International Society for Pharmacoepidemiology (ISPE) Special Task Force on RWE (Berger 2017), including recommendations for stakeholder (e.g., patient, manufacturer) consultation and public study registration and publication.

2. *Capturing other important potential benefits and contextual considerations.*

As part of the proposed updates, ICER has made no significant proposals to the base methodology through which additional dimensions of value would receive a quantified weighting. The proposed updates include, however, the addition of dimensions of value as new categories of "other potential benefits or disadvantages"

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

within assessments of single dose transformative therapies for appraisal by a voting panel. Voting panels, however, may not have the expertise to evaluate value factors in a meaningful way. Many "contextual considerations" can and will have a significant effect on the value of a treatment. ICER's approach is therefore insufficient and does not quantitively incorporate the impact of many important patient-centered factors.

One example of an overlooked factor related to personalized medicine is the consideration of diagnostic testing to help drive treatment safety, efficacy, and efficiency. ICER maintains that "Evaluations of long-term cost-effectiveness are made challenging because of the potential for evolution of devices/diagnostics and the attendant changes in cost, effectiveness, and the types of patients that will be treated." While we appreciate that ICER recognizes the potential for these elements to impact value and the potential for the evolution of treatment value due to devices/diagnostics, the consideration of "contextual considerations" falls short of adequately capturing the value that may be realized due to diagnostic tests. For example, the framework does not explicitly include value factors related to predictive testing to (1) avoid ineffective treatment initially; (2) make an informed change in treatment when patients fail to respond; or (3) determine clinical trial eligibility — all of which are critical elements of the evolving treatment landscape and help build evidence of the value of novel drugs.

Other important value factors further reflect heterogeneity, patient preferences, health care delivery management, and other factors related to individual patient characteristics and care. These must be formally accounted for in value assessment methodologies where possible. While there is no standard methodology in place for quantitatively incorporating these patient-centered factors into assessment results, they will nonetheless play a significant role in the overall value of any treatment. It is critical that newly developed methodologies, such as multi-decision criteria analysis and bayesian network modeling be further developed and tested.

3. *Multiple cost-effectiveness outcome measures.*

We appreciate that ICER has made efforts to broaden its cost-effectiveness analyses, focused on cost per life year gained and cost per quality-adjusted life year (QALY), to permit consideration of alternate, or additional, cost-effectiveness and cost-utility measures.

While the QALY's ability to provide a single measure of the "value" of a treatment makes it a commonly used metric for quantifying health benefits, patients do not receive treatments in isolation. Personalized medicine is a complex, multi-faceted process with patients receiving care along a continuum — from diagnostic testing, clinician and genetic counselor consultation, disease management and monitoring, to medication therapy and hospitalization when necessary. Including the complementary equal value of life years gained (evLYG) measure in assessment methodologies is a step in the right direction, but this measure is also limited. A single measure, such as the QALY, cannot adequately capture true patient-centered value and the broad heterogeneity of clinically relevant characteristics and preferences across patients and diseases. While adding the evLYG measure brings additional considerations into the assessment, it is still reliant on the QALY and therefore not an independent measure. Both metrics are based on averages. It is imperative that ICER consider the heterogeneity of patient populations, even within the same condition. PMC therefore recommends disaggregating the QALY-based metrics and considering a more comprehensive set of value elements that is inclusive and reflects patient heterogeneity as well as personalized medicine services and concepts.

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

4. *Cost-effectiveness thresholds.*

The proposed updates to the framework involve the implementation of a range of incremental cost-effectiveness thresholds and value-based price benchmarks, which are determined based on the average weighting of pre-specified elements or other benefits and contextual considerations voted on and ranked by an independent committee. No threshold range can or should be universally applicable, as thresholds are likely to vary by decision-maker, population, and disease. Furthermore, ICER's current approach of setting a uniform budget impact threshold based on a fixed portion of drug expenditures creates an artificial affordability threshold that could have negative, unintended consequences such as shifting spending toward care strategies that are cheap in the short-term but inefficient over time, thereby moving away from personalized medicine and reducing the value of our health care dollar.

5. *New processes for re-evaluating evidence.*

The proposed updates include revised re-evaluation timelines, pointing to reassessments one year after the publication of a report. PMC applauds ICER for considering re-evaluation sooner than the two-year period previously employed; however, the timeframe should be less arbitrary and more explicitly tied to new and evolving evidence regarding a given treatment. Arbitrary timelines for consideration of evidence to trigger a re-evaluation assumes that information will become available at a single point in time. Evidence, however, continuously accumulates over time.

The personalized medicine field is evolving too rapidly to accurately maintain a current assessment of treatment value with a single static period between assessment review and associated updates. For example, shortly after ICER published its report on the value of non-small cell lung cancer treatments, technology advancements related to the use of biomarkers to help guide treatment decisions altered the value proposition for some treatments. For a value assessment framework to remain useful over time, evidence reports need to be considered for updating routinely. ICER should provide criteria for when evidence reviews will be updated based on new evidence, particularly as it relates to diagnostic stratification or other contextual factors. The framework should consistently employ methods to assess value at interim time points over a longer term using practice-based evidence wherever possible. Additionally, PMC recommends that ICER provide a mechanism for external stakeholders to request re-evaluation when new data emerges.

7. *Evidence ratings.*

While ICER has proposed an expansion of evidence rating categories, the methods still do not adequately reflect the relative contribution to the overall long-term value of contextual considerations, and other benefits and disadvantages. The impact of these considerations remains subjective. For example, the consideration of predictive diagnostic testing results can considerably reduce uncertainty related to treatment safety and efficacy in some cases. However, ICER's current approach leaves the consideration of these factors up to the discretion of a voting panel, which may not have the expertise or appropriate context to meaningfully evaluate them. Because it is heavily dependent upon the perspectives and decisions of a small group, this valuation approach is not transparent or consistent. Furthermore, the approach may be insufficient to incorporate the impact of important patient heterogeneity considerations.

Relying on subjective contextual considerations risks applying false weight and a false sense of precision and accuracy to these important value elements. Many evidence ratings would simply not address the complexity

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

within a diverse population. ICER's evidence ratings may therefore undervalue innovative personalized medicines, as it may be particularly problematic for newer treatments and therapies where evidence of sub-population benefits may not be considered at the time of assessment.

PMC strongly advocates that ICER devise a method to formally account for these elements with a fully transparent valuation approach that incorporates viewpoints from all stakeholders and assures that emerging evidence of patient heterogeneity is appropriately considered in evaluations.

Evidence ratings should concentrate not just on selection bias, uncertainty, and reliability but also measures of heterogeneity. ICER states that when dealing with particular individuals, "decisions will be made with other sources of data in mind." However, with increased evidence of genetic and epigenetic factors on the relative effectiveness of different therapies as well as the growing importance of personalized medicines in the health care industry, an evidence rating system that does not consistently factor in heterogeneity will have limited relevance.

8. *Crosswalk between ICER evidence ratings and those of the German health technology assessment system.*

As part of the proposed updated to the 2020 framework, ICER would introduce evidence ratings designed to crosswalk to the German Institute for Quality and Efficiency in Health Care (IQWiG) evaluation approach. The IQWiG system, which utilizes distinct methodologies and assumptions, can provide valuable conceptual considerations for ICER as it evolves its assessment methodologies, but a direct crosswalk comparison could be misleading as it might lead to a false impression that the two outputs are coordinated and relevant to one another in all settings. For example, the IQWiG system may have better processes to contend with differing value parameters related to different conditions such as rare and ultra-rare diseases, and these processes should be examined to determine how they can be implemented into ICER's methodologies. These processes, however, should be put into context as related to the current ICER evaluation system, which is ill-equipped to account for differing condition-specific value parameters. Such a comparison could create an opportunity for misuse of assessment measures to undermine the underlying value parameters associated with IQWiG evaluations.

Conclusions/Recommendations

Personalized medicine has a profound impact on the comparative value of treatments, and now is the time for ICER to formally address, take into consideration, and clearly delineate the methods for integrating personalized medicine products, services, and concepts into the framework. We look forward to working with you to improve ICER's process so that the principles of personalized medicine are incorporated into its work. With these five principles in mind, the framework can better reflect and serve the needs of the health care community:

1. Considerations related to personalized medicine, such as heterogeneity of treatment effect, treatment efficiency (i.e., potential cost savings by avoiding less effective treatment or adverse side effects), and individual values and circumstances can significantly impact comparative clinical effectiveness and value assessment.

2. Diagnostic testing must be considered an integral part of the assessment of the value of treatment options where heterogeneity of treatment effect can be assessed, or efficacy and/or safety information

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

can be obtained.

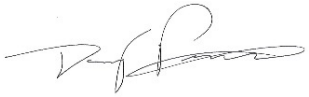
3. Methods for assessing value must consider RWE that can provide insight on emerging or evolving value elements over time.

4. Valuation approaches should be transparent and consistent, include a broad array of benefits that are important to patients and society, and adequately account for population diversity through consideration of patient heterogeneity.

5. All stakeholders must be engaged, and multiple perspectives must be integrated throughout the value assessment process.

PMC appreciates the opportunity to provide these comments. PMC and ICER are united by a shared goal of providing patients and health care providers with valuable technologies that are safe and effective and will best serve the needs of patients and the health care system. If you have any questions about the content of this letter, please contact PMC at dpritchard@personalizedmedicinecoalition.org or 202-787-5912. We look forward to further opportunities to provide feedback.

Sincerely,



Daryl Pritchard
Senior Vice President, Science Policy
Personalized Medicine Coalition

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778