
ICER Value Framework

Discussion of Revision Options for v2017-2019
February 13, 2017



INSTITUTE FOR CLINICAL
AND ECONOMIC REVIEW

Outline

- ICER value assessment framework
 - Purpose
 - Guiding principles
- Public and stakeholder comment
- Proposals for revision to the value framework and associated methods
- Next steps

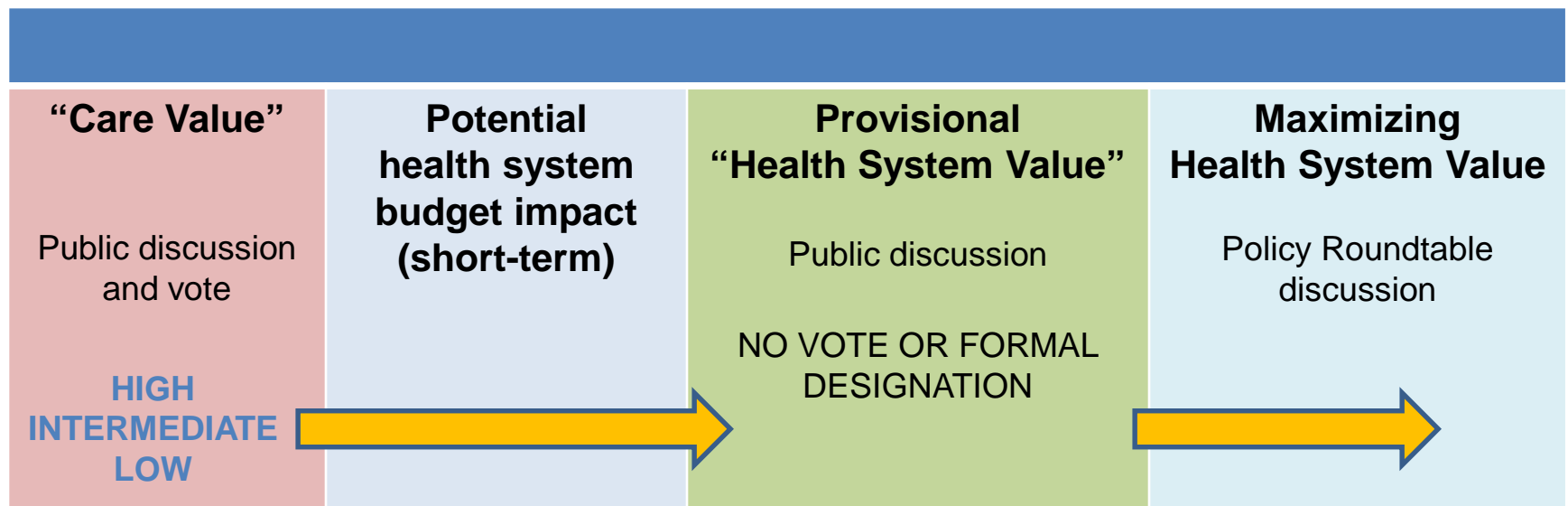
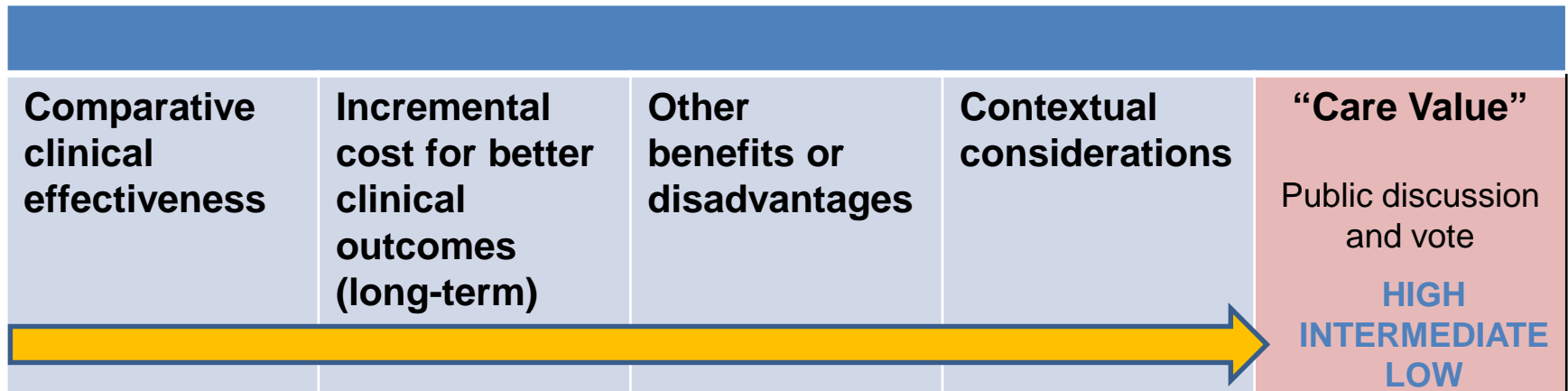
Guiding Principles

- Choices that are made in health care must address the reality that there will always be trade-offs and dilemmas over how to organize and pay for care given the available resources within a health system.
- Rigorous thinking about evidence can prevent the kind of waste that strains our ability to provide high-value care for all patients.
- Value, price, and coverage: the grand bargain

The ICER Value Framework: Purpose

- Takes a “population” level perspective as opposed to trying to serve as a shared decision-making tool to be used by individual patients and their clinicians.
- Even with its population-level focus, the ICER value framework seeks to encompass and reflect the experiences and values of patients.

ICER Value Assessment Framework 1.5



Changes to ICER value framework and process 2015-2016

- Importance of “additional benefits” and “contextual considerations” emphasized by designated sections within ICER reports and structured moderation to consider in voting at public meetings
- No vote on provisional health system value
- New messaging added to emphasize that ICER’s value-based price benchmark has two elements: anchor in long-term cost-effectiveness range, and (when relevant), a price representing an “alarm bell” for consideration of mechanisms to manage affordability

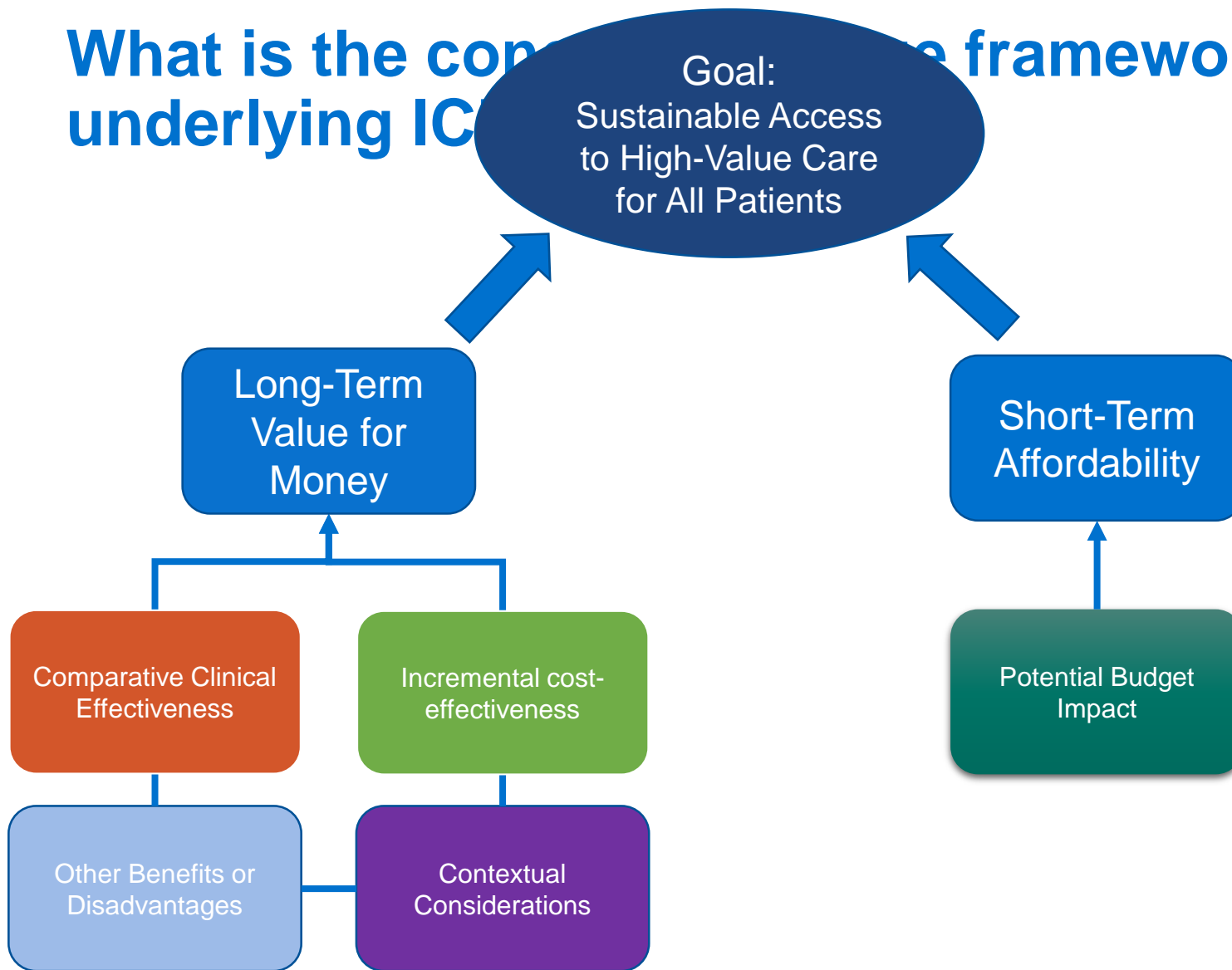
Changes to ICER value framework and process 2015-2016

- Changes in engagement with the patient community and manufacturers
 - Earlier
 - More
 - Longer

Public Comment

- Conceptual terms
 - “Care Value”
 - “Provisional Health System Value”
- Types of evidence
- Integration of “additional benefits or disadvantages” and “contextual considerations”
- The quality-adjusted life year (QALY)
- Potential budget impact
- Report development and meeting process

What is the conceptual framework underlying ICER?



Specific update/revision proposals

- Key distinctions and omissions:
 - Ultra-orphan drugs
 - Therapeutic devices
 - Diagnostics and monitoring systems
 - Delivery system interventions

Specific update/revision proposals

- Comparative clinical effectiveness
 - Continued use of ICER EBM rating matrix and methods
 - ICER re-states its intent to evaluate evidence arising from multiple sources, not just randomized controlled trials (RCTs), that can be useful in judging the comparative clinical effectiveness of different care options.
 - Patient groups inform what outcomes are important, differences across severity, time in disease course, etc.
 - Patient groups inform re: opportunities for using or generating real-world evidence
 - Whenever possible from available data or data provided by manufacturers, ICER proposes to include an evaluation of the heterogeneity of treatment effect for key clinical outcomes.

Incremental cost-effectiveness

- The QALY will remain as the primary measure of clinical benefit for comparisons across different conditions and treatments
- ICER will use a broader range of cost-effectiveness thresholds between \$50,000 and \$150,000 per QALY to guide considerations of long-term value for money.
 - Societal willingness to pay (1-3x per capita GDP)
 - Individual WTP (~2x annual salary)
 - Empiric opportunity cost estimates (\leq 1x per capita GDP)
- Estimated prices net of discounts and rebates

Other benefits or disadvantages and contextual considerations

- Public comments often recommended making them more tangible and possibly quantifying them as part of the cost/QALY
- Considered
 - More explicit list but leave qualitative for appraisal committees to integrate in voting on value
 - Formal multi-criteria decision analysis (MCDA)
 - “Staircase” model for cost/QALY thresholds
- Proposed: modified version of MCDA

Proposed modified MCDA

- ICER reports will explicitly delineate other benefits or disadvantages and contextual considerations as the following 10 elements:
 - Unmeasured patient health benefits
 - Relative complexity of the treatment regimen that is likely or demonstrated to significantly affect adherence and outcomes
 - Impact on productivity and ability of the patient to contribute to personal and national economic activity
 - Impact on caregiver burden
 - Impact on public health
 - New mechanism of action that is likely to help patients who have not responded to other treatments
 - Severity of the untreated condition
 - Lifetime burden of illness
 - Lack of availability of any previous treatment for the condition
 - Other ethical, legal, or social considerations that might strongly influence the overall value of an intervention to patients, families and caregivers, the health system, or society

Proposed modified MCDA

- The ICER report will include evidence and other information relevant to these value elements, and before voting at the public meeting further input will be obtained from patient representatives, clinical experts, and other stakeholders.
- Appraisal committees will be asked to consider these 10 areas and indicate their relative score for each on a visual analogue scale from “least” to “most.”
- Appraisal committees will then be asked to give an overall ranking on a quantitative scale from 1-5 of the relative contribution to overall long-term value for money of all “other benefits or disadvantages and contextual considerations.”

Proposed modified MCDA

- The average weighting from 1-5 will be used to assign a single ICER from within the range of \$50,000-\$150,000 per QALY included in the draft evidence report.
- This single ICER will be used as the threshold at which a single value-based price benchmark will be calculated.

Other benefits/contextual considerations average score	Associated incremental cost-effectiveness ratio used as threshold for final value-based price benchmark
1	\$50,000 per QALY
2	\$75,000 per QALY
3	\$100,000 per QALY
4	\$125,000 per QALY
5	\$150,000 per QALY

Proposed modified MCDA and the ICER value-based price benchmark

- The final ICER value-based price benchmark will be a single price based on the price needed to achieve the weighted incremental cost-effectiveness ratio determined by the appraisal committee at the public hearing.
- ICER Final Reports and press releases will also include the broader price range needed to achieve thresholds of \$50,000-\$150,000 per QALY.
- Compared to this single cost/QALY threshold, if the base case cost/QALY for the treatment is:
 - > \$25,000 per QALY higher = “low” long-term value for money
 - > \$25,000 per QALY lower = “high” long-term value for money
 - Otherwise “intermediate” long-term value for money

Proposed modified MCDA: application to rating of long-term value for money

Other benefits/contextual considerations average score	Associated incremental cost-effectiveness ratio used as threshold for final value-based price benchmark
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Public Comment 5: Potential Budget Impact

- Maintain as a part of value assessment
- Eliminate it entirely
- Separate from value assessment
- Eliminate any kind of “alarm bell” threshold
- Create another threshold linked to spending within a single budget category, e.g. specialty pharmaceuticals
- Longer time horizon
- Shorter time horizon

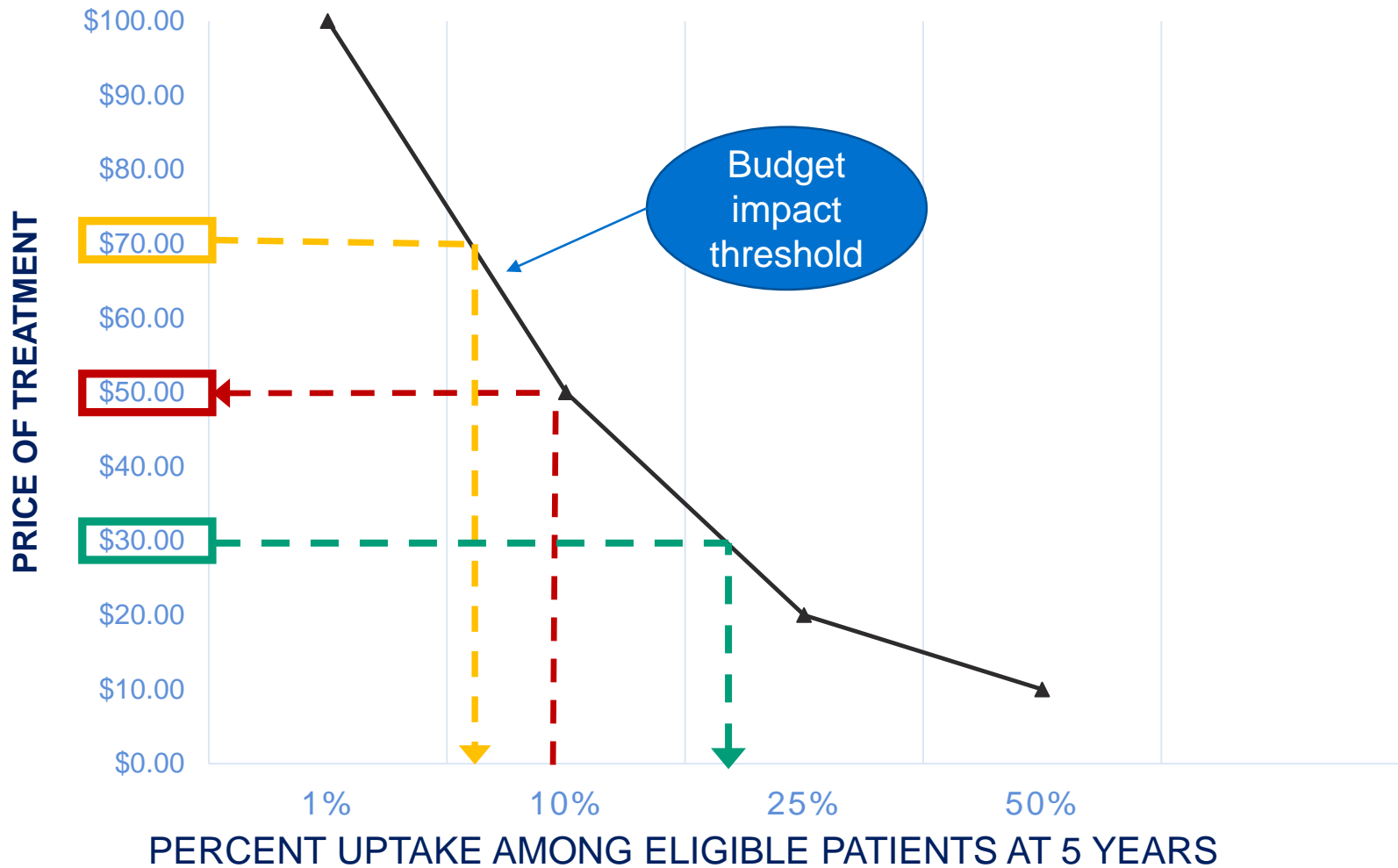
Potential Budget Impact proposals

- Extensive discussions have affirmed the relevance of linking a potential budget impact threshold to national GDP growth.
- ICER will no longer attempt to estimate the uptake of a new intervention.
- ICER will present information that will allow stakeholders to ascertain the potential budget impact of a new service according to a wide range of assumptions on price and uptake.

Potential Budget Impact threshold 2017-2018

Item	Parameter	2015-2016 Estimate	2017-2018 Estimate	Source
1	Growth in US GDP, 2017 (est.) +1%	3.75%	3.20%	World Bank, 2016
2	Total personal medical health care spending	\$3.08 trillion	\$2.71 trillion	CMS NHE, 2016
3	Contribution of drug spending to total health care spending	13.3%	17.7%	CMS NHE, 2016; Altarum Institute, 2014
4	Contribution of drug spending to total health care spending	\$410 billion	\$479 billion	Calculation (Row 2 x Row 3)
5	Annual threshold for net health care cost growth for ALL drugs	\$15.4 billion	\$15.3 billion	Calculation (Row 1 x Row 4)
6	Average annual number of new molecular entity approvals	34	33.5	FDA, 2016
7	Annual threshold for average cost growth per individual new molecular entity	\$452 million	\$457.5 million	Calculation (Row 5 ÷ Row 6)
8	Annual threshold for estimated potential budget impact for each individual new molecular entity	\$904 million	\$915 million	Calculation (doubling of Row 7)

POTENTIAL BUDGET IMPACT SCENARIOS



Potential budget impact: Experience to date

- Exceeded alarm bell threshold
 - PCSK9 inhibitors for high cholesterol
 - Entresto for heart failure (over by 9%)
 - CardioMEMS system for heart failure
 - Ocaliva for NASH
- Did not exceed alarm bell threshold
 - Nucala for severe eosinophilic asthma
 - New drugs for multiple myeloma
 - Tresiba for diabetes
 - Ocaliva for primary biliary cholangitis
 - Diabetes prevention programs
 - Palliative care in the outpatient setting

ICER “affordability and access alert”

- ICER will include as part of its final report an “affordability and access alert” if discussion among stakeholders at the meeting of ICER’s independent appraisal committees suggests that utilization driven by clinical need, at estimated net pricing, would exceed the budget impact threshold without active intervention by insurers and others to limit access to the treatment.

NOT A BUDGET CAP!

- The purpose of our potential budget impact analyses and any “affordability and access alerts” are not to suggest a budget cap on spending for a particular drug, or for drugs as a category of spending in the US health care system.
- The purpose is to signal to stakeholders and policy makers that the amount of added health care costs associated with a new service may be difficult for the health system to absorb over the short term without displacing other needed services or contributing to rapid growth in health care insurance costs that threaten sustainable access to high-value care for all patients.

Open Public Comment 1: Process

- Greater inclusion of patients throughout
 - More expansive role during key scoping phase
 - Request for more detailed patient input guide
 - Requests for templates and other materials
- Greater transparency in modeling – executable models
- More time for every phase of the report development process to allow better engagement/comment
- Revise reports regularly
 - Enhanced messaging of time-limited purpose of reviews

Report development and meeting process

- Preliminary report findings from the systematic review and economic modeling are now discussed with manufacturers and patient groups prior to posting of the first draft review for broader public comment.
- All parameter inputs and assumptions shared with stakeholders; exploring options for access to executable models
- Patient rep(s) and clinical experts will join the independent committee for the entire meeting, being available for questions and able to make comments during the presentation of the evidence and deliberation prior to voting.
- Patient groups will be given the opportunity to present the results of their own evidence generation through patient-reported outcomes and surveys on other benefits or disadvantages.
- Patient and manufacturer engagement guides also posted for public comment.

Next steps

- 60-day comment period closes April 3
- Posting of finalized updates approximately April 15
- Implementation with reports beginning May 1 but some elements woven into ongoing reports
- Experience with new methods and continued dialogue with all stakeholders
- Next planned formal update 3rd quarter 2019