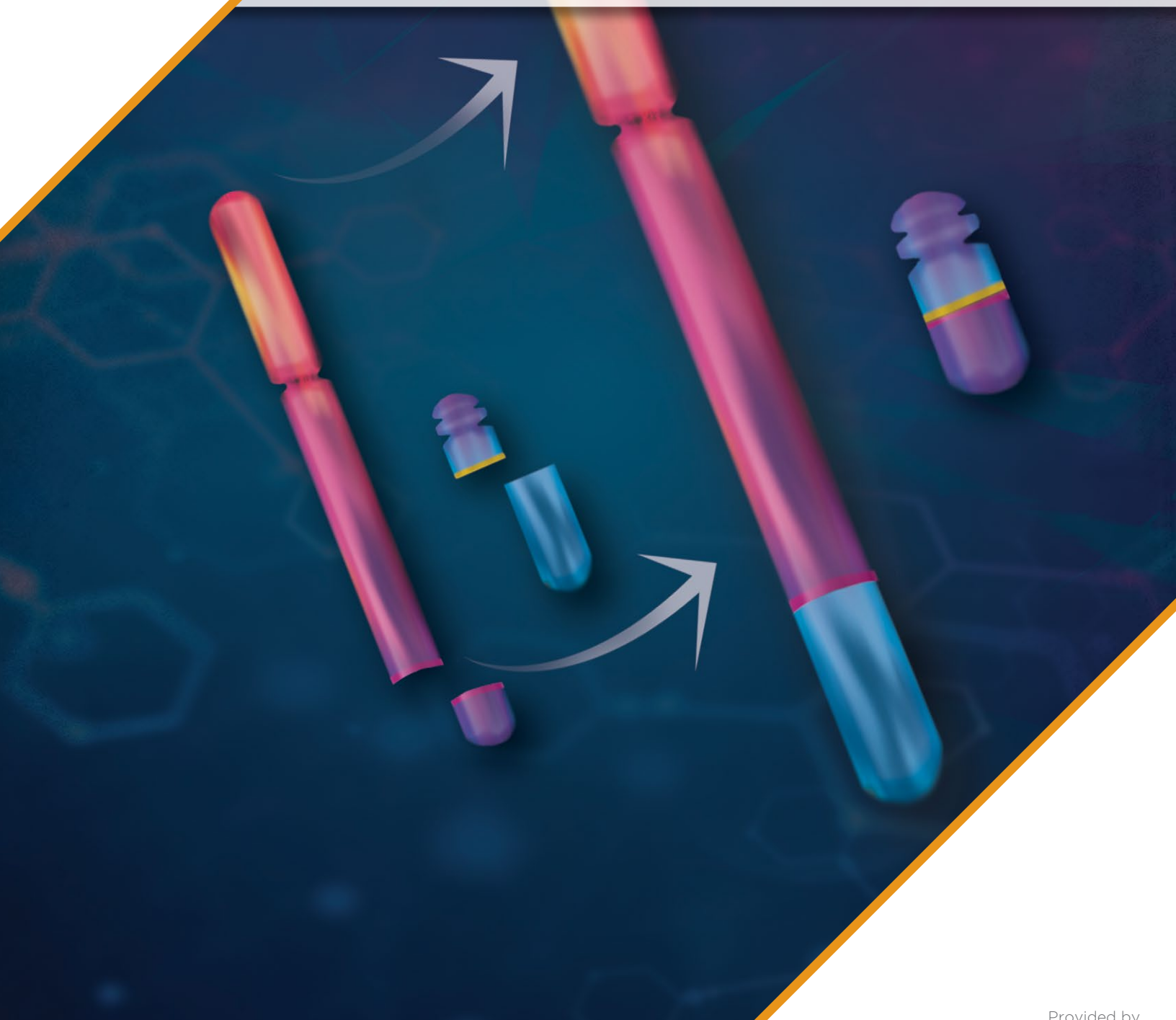
AXIS Medical Education

# Response Matters:

## Transforming the Standard of Care in CML by Mastering Response-Guided Treatment

### A Shared Decision-Making Guide



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AXIS Medical Education

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# Shared Decision-Making

## WHAT IS SHARED DECISION-MAKING?

Shared decision-making (SDM) occurs when a healthcare provider and a patient work together to make a healthcare decision that is best for the patient. Optimal decision making takes into account evidence-based information about available options; the provider's knowledge and experience; and the patient's values, goals and preferences. Patients and their families/caregivers who are engaged in an SDM process are more likely to arrive at a treatment decision that works best for all those involved.

## WHY IS SDM IMPORTANT IN CHRONIC MYELOID LEUKEMIA?

Making informed decisions about treatment for chronic myeloid leukemia (CML) is challenging and can be daunting to the patient, who may be overwhelmed by therapeutic options and how they differ based on benefits, risks, and potential complications. Quite often, the choice of treatment may hinge on patient preferences. Patients and caregivers can play a collaborative and integral role with their healthcare team in determining a course of therapy that is in line with their lifestyles, goals, and desires for disease control.

Communication among patients/caregivers and providers can facilitate SDM, helping to improve patient adherence to therapy, enhance satisfaction with care delivery, and elevate quality of life. By successfully engaging with the healthcare team through SDM, patients may experience better therapeutic outcomes and higher-quality care.

Optimal care of CML involves the use of effective therapies that are supported by the latest evidence and guidelines, selected through a SDM process and individualized to each patient's needs.

# Methodologies for Testing for Molecular Alterations and Biomarkers

For years, the use of real-time quantitative reverse transcription polymerase chain reaction (RT-qPCR) has been used to evaluate treatment response in patients with CML by assessing reduction of *BCR-ABL1* transcript levels and providing more accurate gauging of depth of response relative to previous hematologic and cytogenetic methods.[1] However, this may be susceptible to low precision and poor sensitivity when transcript levels are low.[2] Additional methods that are more sensitive and accurate, such as digital PCR assessment, are also being studied, but these are not standardized and not yet widely available.

Molecular testing is also important in identifying potential point mutations in the kinase domain of BCR-ABL1 in patients that have not achieved a desired response to TKI therapy. A comparison of the advantages and disadvantages of these approaches is included below:

### Advantages and Disadvantages of Techniques to Evaluate BCR-ABL1 Kinase Domain Mutations (adapted from Table 2, Soverini et al.)[1]

| Technique | Advantages | Disadvantages |
|---|---|---|
| **Sanger sequencing** | • Simple to use and readily available | • Limited sensitivity |
| **Next generation sequencing** | • Greater sensitivity than Sanger sequencing<br>• Capacity to evaluate entire kinase domain for mutations<br>• Facilitates clonal analysis | • Lack of standardization<br>• Technology still evolving<br>• Requires pooling of multiple (8-10) samples to create cost effectiveness<br>• Limited access<br>• Background noise at lower sensitivity from RT-PCR and sequencing errors |
| **Digital PCR** | • Highest level of sensitivity<br>• Relatively inexpensive, simple to use, and quick | • Lack of standardization<br>• Only useful for a limited number of mutations<br>• Additional considerations for identification of compound mutations |

# Explaining the Probabilities of Benefits/Risks of Therapy and the Tactics for Weighing Benefits/Risks of Therapy Selection

For patients and clinicians alike, it is essential to weigh the risks and benefits of different treatment options and to be aware of the potential for not only acute side effects, but long-term side effects of different treatment options. Individual patient goals and preferences should be considered, including desire for curative treatment. The effects of treatment options on patient quality of life and independence are crucial. According to the American Society of Clinical Oncology, there are several tactics that may help to appropriately weigh the balance of risks and benefits of different treatment options, including:[3]

- Getting a second opinion
- Understanding the latest guideline recommendations
- Incorporating other decision-making tools
- Encouraging patient discussions with people they trust (clergy, family, social workers, etc.)
- Understanding statistical data for key outcomes and what these may mean (or not mean) for each individual patient

Additional considerations may be found at the Cancer.Net website:[3]
https://cancer.net/navigating-cancer-care/how-cancer-treated/making-decisions-about-cancer-treatment

# The AXIS 6 Ease ("E's") to SDM

### ENSURE

Ensure you see and treat the patient as an individual not a disease.

### ELEVATE

Elevate the patient-centric experience and improve satisfaction with care.

### ENABLE

Enable a long-term personal connection with your patients.

### ESTABLISH

Establish co-created treatment plans that align medical evidence with patient preferences to foster adherence and optimize outcomes.

### ELICIT

Elicit patient/caregiver preferences, values, and goals for therapy.

### EVALUATE

Evaluate the risk/benefits and costs of treatment so they are aligned with patient expectations.

# Summary of Indications and Guidelines

| Agent | CML Indications (from Prescribing Information) | Select NCCN Guideline Statements[4] |
|---|---|---|
| **Asciminib** | • Adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with ≥2 tyrosine kinase inhibitors (TKIs)<br>• Adult patients with Ph+ CML in CP with the T315I mutations | • Asciminib is a treatment option for CP-CML patients with the T315I mutation and/or CP-CML with resistance or intolerance to ≥2 prior TKIs<br>• Contraindicated in patients with the following *BCR::ABL1* kinase mutations – A337T, P465S, or F359V/I/C |
| **Bosutinib** | • Adult patients with newly-diagnosed CP Ph+ CML<br>• Adult patients with chronic, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy | • 2G TKI as a preferred (category 1) primary treatment for CP-CML<br>• Listed as a preferred regimen for AP-CML<br>• One of three options recommended in second line for patients with disease resistant to imatinib, taking into account *BCR::ABL1* kinase domain mutation status<br>• Contraindicated in patients with the following *BCR::ABL1* kinase mutations – T315I, V299L, G250E, or F317L (min. activity against F317L) |
| **Dasatinib** | • Adult patients with newly-diagnosed CP Ph+ CML<br>• Adults with CP, AP or myeloid or lymphoid BP Ph+ CML with resistance to/intolerance of prior therapy including imatinib | • 2G TKI as a preferred (category 1) primary treatment for CP-CML<br>• Listed as a preferred regimen for AP-CML<br>• One of three options recommended in second line for patients with disease resistant to imatinib, taking into account *BCR::ABL1* kinase domain mutation status<br>• Contraindicated in patients with the following *BCR::ABL1* kinase mutations – T315I/A, F317L/V/I/C, or V299L |
| **Imatinib** | • Adult and pediatric patients with newly-diagnosed CP Ph+ CML<br>• Patients with Ph+ CML in blast crisis or AP or in CP after failure of interferon-alpha therapy | • 1G TKI as a preferred (category1) primary treatment for CP-CML with low-risk score; "other recommended regimen" for those with intermediate/high-risk score<br>• Not recommended for disease progression on prior TKI therapy<br>• "Useful in certain circumstances" for AP CML, if 2G or 3G TKI contraindicated<br>• Numerous mutational contraindications |
| **Nilotinib** | • Adult and pediatric patients (≥1 year of age) with newly-diagnosed CP Ph+ CML<br>• Adult patients with CP and AP Ph+ CML resistant to or intolerant to prior therapy that included imatinib<br>• Pediatric patients ≥1 year of age with CP Ph+ CML and AP CML resistant or intolerant to prior TKI therapy | • 2G TKI as a preferred (category 1) primary treatment for CP-CML<br>• Listed as a preferred regimen for AP-CML<br>• One of three options recommended in second line for patients with disease resistant to imatinib, taking into account *BCR::ABL1* kinase domain mutation status<br>• Contraindicated in patients with the following *BCR::ABL1* kinase mutations – T315I, Y253H, E255K/V, or F359V/C/I |
| **Ponatinib** | • Adult patients with CP CML with resistance or intolerance to ≥2 prior TKIs<br>• Adult patients with AP or BP CML for whom no other TKIs are indicated<br>• Adult patients with T315I-positive CML (CP, BP, or AP) | • Preferred treatment option for patients with T315I mutation in any phase<br>• 3G TKI option for patients with CP CML in patients with resistance or intolerance to ≥2 TKIs or patients with AP or BP CML for who no other TKI is indicated<br>• Listed as a preferred regimen for AP-CML<br>• Preferred for patients with no identifiable *BCR::ABL1* mutations |

# Overview of Topline Trial Results to Help Facilitate Discussion and Collaborative Decision-Making for Patients With CP-CML

## SECOND-LINE AND SUBSEQUENT THERAPY (Table adapted from NCCN Guidelines for CML, Version 1.2024)[4]

| Agent | Study | Topline Trial Results |
|---|---|---|
| **Asciminib** | Hochhaus et al.[5] | Asciminib 40 mg twice daily in patients treated with/ multiple TKIs<br>• MMR at week 96: 38% with asciminib vs. 16% with bosutinib<br>• CCyR at week 96: 50% with asciminib vs. 16% with bosutinib<br>• 2-year estimated progression-free survival: 94% vs. 91%<br>• 2-year estimated overall survival: 97% vs. 99% |
| **Bosutinib** | Cortes et al.[6] | Bosutinib 500 mg once daily after failure of imatinib plus dasatinib and/or nilotinib<br>• 4-year imatinib/dasatinib resistant: OS: 67%, MCyR 39%, CCyR 22%<br>• 4-year imatinib/dasatinib intolerant: OS: 80%, MCyR 42%, CCyR 40%<br>• 4-year imatinib/nilotinib resistant: OS: 87%, MCyR 38%, CCyR 31% |
| **Dasatinib** | Shah et al.[7] | Dasatinib 100 mg once daily for patients intolerant or resistant to imatinib<br>• 7-year MMR: 46%<br>• 7-year PFS: 42%<br>• 7-year OS: 65% |
| **Nilotinib** | Giles et al.[8] | Nilotinib 500 mg twice daily for patients intolerant or resistant to imatinib<br>• 4-year OS: 78%<br>• 4-year PFS: 57%<br>• 4-year MCyR: 59%<br>• 4-year CCyR: 45% |
| **Ponatinib** | Cortes et al.[9] | Ponatinib in patients resistant to or intolerant of multiple TKIs or with BCR-ABL1 T315I mutation<br>• 45 mg once daily cohort: 3-year PFS 73%, 3-year OS 89%<br>• 30 mg once daily cohort: 3-year PFS 66%, 3-year OS 89%<br>• 15 mg once daily cohort: 3-year PFS 70%, 3-year OS 92% |

## RATIONALE FOR THERAPY SELECTION

First-line choice of treatment for patients with chronic phase CML requires assessment of several disease- and patient-specific factors, including appraisal of patient comorbidities and risk for adverse events, prognostic scores, patient lifestyle considerations, and concomitant medication use.[10] Treatment cost and access are also important governing factors to consider.[10] Regular monitoring and timely identification of signs of treatment intolerance or failure may lead to appropriate switching when necessary and optimization of outcomes.

Anticipated efficacy of other options is a key factor driving subsequent selections.[4,11] Mutational analysis is an essential component of this determination. If patients treated with imatinib (a 1G TKI) develop resistance, then a 2G TKI may be used as long as mutational analysis does not show the T315I mutation.[4]

If the second or third line of treatment does not achieve the desired response, then the choice of TKI should again be based on mutational analysis, with consideration of allogeneic HCT. In addition, other factors such as patient comorbidities, drug interactions, suboptimal adherence, and prior adverse events should be accounted for in treatment selection.[12] Omacetaxine is available for patients who have developed resistance to multiple TKIs.[4]

# Short- and Long-term Summaries of Adverse Events with Mitigation and Management Strategies

The selection of specific TKIs sets the table for baseline and longitudinal monitoring for adverse events.[13]

TKIs have a range of potential associated adverse events, including (but not limited to) hematological, cardiovascular, gastrointestinal, pulmonary, dermatologic, renal, hepatic, and musculoskeletal challenges.[13]

Individual agents have different toxicity profiles; the greater risk of each class of adverse event (e.g., cardiovascular) should warrant greater vigilance for those adverse events.[13]

Partnership with primary care, general internal medicine, subspecialties such as cardiology and cardio-oncology, can also help to identify manage AEs.[13]

Specific approaches for risk management with individual agents for CML such as asciminib, bosutinib, dasatinib, imatinib, nilotinb, omacetaxine, and ponatinib are described in prescribing information, as well as the current NCCN guidelines for Chronic Myeloid Leukemia, available at:[4] https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf.

# Glossary of Key Terms

### Accelerated phase (AP)[14]
An advanced phase of CML, with many patients having 10-19% blasts in blood and bone marrow, or >20% basophils in peripheral blood

### Allogeneic Hematopoietic Cell
Transplantation (Allo HCT)4 Potentially curative treatment for CML in which patients receive healthy hematopoietic cells from a donor; indicated for patients with AP or BP CML at presentation or disease progression to AP CML or BP CML while receiving TKI therapy. May be a consideration for patients with CP CML who have developed TKI resistance or those who are resistant/intolerant to all TKIs (not a first-line recommendation for CP-CML).

### BCR-ABL1 inhibitor[15]
Therapeutic agents for CML that target the BCR-ABL1 oncoprotein and its constitutively active tyrosine kinase domain. These may act by targeting areas such as the ATP-binding site and the myristoyl-binding pocket.

### Blast phase (BP)[13]
Also known as “blast crisis”; an advanced phase of CML, in which there are ≥20% blasts in blood or bone marrow.

### Chronic phase (CP)[13]
Phase of CML in which blood and bone marrow contain <10% blasts

### Complete cytogenetic response (CCyR)[4]
Treatment response characterized by an absence of Ph-positive metaphases

### Deep molecular response (DMR)[4]
Treatment responses conveying varying depth:

MR4.0 (4-log reduction): *BCR::ABL1* (IS) ≤ 0.01%
or

MR4.5 (4.5-log reduction): *BCR::ABL1* (IS) ≤0.0032%

### Gatekeeper mutation[16,17]
Mutation of key residues of *BCR::ABL1* that serves as an escape mechanism for cancer cells by conferring resistance to many TKIs; the T315I mutation is a key example in CML.

### Major molecular response (MMR)[4]
Treatment response characterized by *BCR::ABL1* (IS) ≤0.1% or ≥3-log reduction in *BCR::ABL1* transcripts from the standardized baseline, if qPCR (IS) is not available

### Treatment-free remission (TFR)[18]
TKI therapy for CML has been discontinued and a deep molecular response is maintained without needing to resume therapy

# Sample Questions for Clinicians to Pose to Patients to Facilitate Shared Decision-Making[19]

- What do you already know and understand about CML?
- Are there any aspects of treatment that you are worried about?
- What would you like most from your treatment?
- What is your #1 priority that we accomplish during our visit today?
- What has happened with you since our last visit?
- Are you able to tolerate the treatment we've chosen? If not, why not? How can we provide improved support to enhance your treatment?
- Do you understand the different treatment choices? What else would you like to know about them?
- Do you understand why we've chosen this treatment? What else would you like to know about it?
- Do you have any questions about the benefits or risks of the different treatments we are considering for your disease?
- Are you able to make a decision now, or do you need more time to think about it?
- Would you like to be involved with a patient/caregiver support group?
- How do feel? Are you experiencing any symptoms?
- Are you experiencing any side effects related to your treatment? How has this impacted your lifestyle and quality of life?
- Is your condition interfering with your work, social events, or everyday activities at home?
- What goals do you have regarding your cancer treatment? Have these goals changed since our last visit? It might be:
    - Keeping the symptoms of disease under control
    - Minimizing risks and side effects from treatment
    - Finding a treatment with a dosing/administration option that's easy and convenient
    - Selecting a treatment that is cost effective
- What is most important to you/your family as we discuss current or new treatment options? It might be:
    - Keeping out-of-pocket costs low
    - Resolving disease symptoms
    - Avoiding treatment-related adverse events
    - Maintaining a specific level of functionality
    - Improving quality of life

# Sample Questions for Patients to Pose to Clinicians to Facilitate Shared Decision-Making[20,21]

- Will you tell me about the risks and benefits of the different treatments that we are talking about?
- How do these treatments work?
- What can I expect from the treatments that we are discussing?
- Are the treatment options that you are presenting covered in guidelines, and if so, can you tell me where I might be able to find more details?
- Is there a treatment option that you prefer, and if so, why?
- Are there any ongoing clinical trials that I might benefit from? If there are, where can I learn more about them?
- How will my other health problems be influenced by the treatment that we select?
- If I want to consult another physician or other providers before making a treatment decision, do you have any recommendations?
- What are the timelines and duration of the treatment options that we are discussing?
- What are the financial costs of the treatments, and what financial burden will these present to me?

Additional questions to pose to your clinician regarding testing, diagnosis, care team experience, options, treatment, side effects, pregnancy, hematopoietic cell transplants, and clinical trials are available from the NCCN Guidelines for Patients (Chronic Myeloid Leukemia), pages 50-57. This document is available at: https://www.nccn.org/patients/guidelines/content/PDF/cml-patient.pdf.

Potential questions to pose to the healthcare team are also available at the Cancer.Net website, https://www.cancer.net/cancer-types/leukemia-chronic-myeloid-cml/questions-ask-health-care-team.

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# Documenting SDM

The OPTION scale, or "observing patient involvement," was developed specifically for measuring the extent and quality of integrating SDM by clinical professionals. One clinician uses this tool to observe the other during a patient encounter and "scores" their ability to engage the patient in decision making during that visit.

The OPTION scale is one example of a tool that could be integrated into clinical practice to document that SDM occurs with each patient encounter. The OPTION scale uses items to score each patient encounter on a scale of 0 (behavior is not observed) to 4 (behavior is exemplary).

Please consider integrating the OPTION instrument below to document that SDM occurs across your breast cancer patient population. Documenting that SDM occurs in clinical practice can enhance your reimbursement under the Quality Payment Program parameters.

## THE OBSERVER OPTION - *MEASURE SCORE SHEET*

Date _____ Clinician Name _____

**0** No effort (Zero effort observed)

**1** Minimal effort (Effort to communicate could be implied or interpreted)

**2** Moderate effort (Basic phrases or sentences used)

**3** Skilled effort (Substantive phrases or sentences used)

**4** Exemplary effort (Clear, accurate communication methods used)

### *Item 1*

The clinician **draws attention to or confirms** that different CML treatments or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

### *Item 2*

The clinician reassures the patient or re-affirms that the clinician **will support the patient to become informed or deliberate** about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

### *Item 3*

The clinician **gives information or checks understanding about the options** that are considered reasonable (this can include taking no action) to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

### *Item 4*

The clinician makes an effort to **elicit the patient's preferences** in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

### *Item 5*

The clinician makes an **effort to integrate the patient's elicited preferences** as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.

| 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

Elwyn G, Edward A, Wensing M, et al. Shared decision making: developing the OPTION scale for measuring patient involvement. *Qual Saf Health Care.* 2003;12:93-99.

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