

Mood Disorders Society of Canada
Société pour les troubles de l'humeur du Canada

Blind Spots and Bias in HTA: **Patient Centred Drug Assessment** **to Unlock Better Psychiatric Drug Access**

C D A - A M C S Y M P O S I U M 2 0 2 6

MOOD DISORDERS SOCIETY OF CANADA ACCESS TO MEDICATIONS WORKING GROUP

Panel Session: 10:15-11:30 am EST; Thursday, April 23, 2026

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Aimée Tran Ba Huy

National Project Coordinator, Mood Disorders Society of Canada

As a non-profit charitable organization, Mood Disorders Society of Canada (MDSC) does not receive any core operational government funding. MDSC relies on donations and project financial support to enable it to conduct important patient-centered activities, such as speaking on this panel. MDSC does receive project funding from the pharmaceutical industry, as well as from corporations, research organizations, government, foundations, and individual supporters.



Pierre Blier, MD, PhD, FRSC

Professor, Department of Psychiatry and Cellular and Molecular Medicine, University of Ottawa

Dr. Pierre Blier has received consultation honoraria and served on advisory boards for Janssen, Otsuka, Lundbeck, and Sunovion. He has received speaker honoraria from AbbVie, Eisai, Janssen, Lundbeck, Otsuka, and Pfizer. He has also received research grants and support from AbbVie, Lundbeck, the Canadian Institutes of Health Research (CIHR), Janssen, and the Ontario Brain Institute. In addition, he has provided expert testimony for IntraCellular Therapies, Otsuka, and Merck..



Adam Haynes

Associate Director, Market Access, Eisai Canada

Adam Haynes is an employee of Eisai Limited. The views and opinions expressed are solely my own and do not reflect the views of Eisai Limited.



Graham Statt

Senior Advisor, Santis Health

Graham Statt is a Senior Advisor with Santis Health and in that role he regularly works with government, patient groups and pharmaceutical companies in both a volunteer capacity, and for compensation, both in terms of overall policy but also advocacy for special medicines. His participation in this panel is welcomed by Santis Health but his views expressed are his own and they do not necessarily represent the official position of Santis Health.



Fred Horne

Senior Advisor, 3Sixty Public Affairs Inc.

No relevant financial or non-financial disclosures.



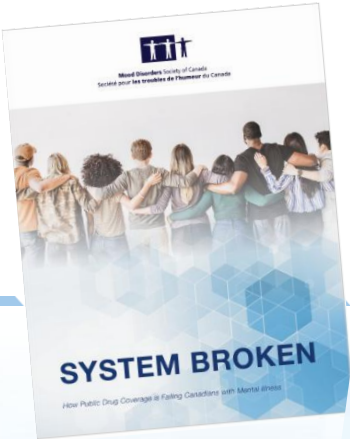
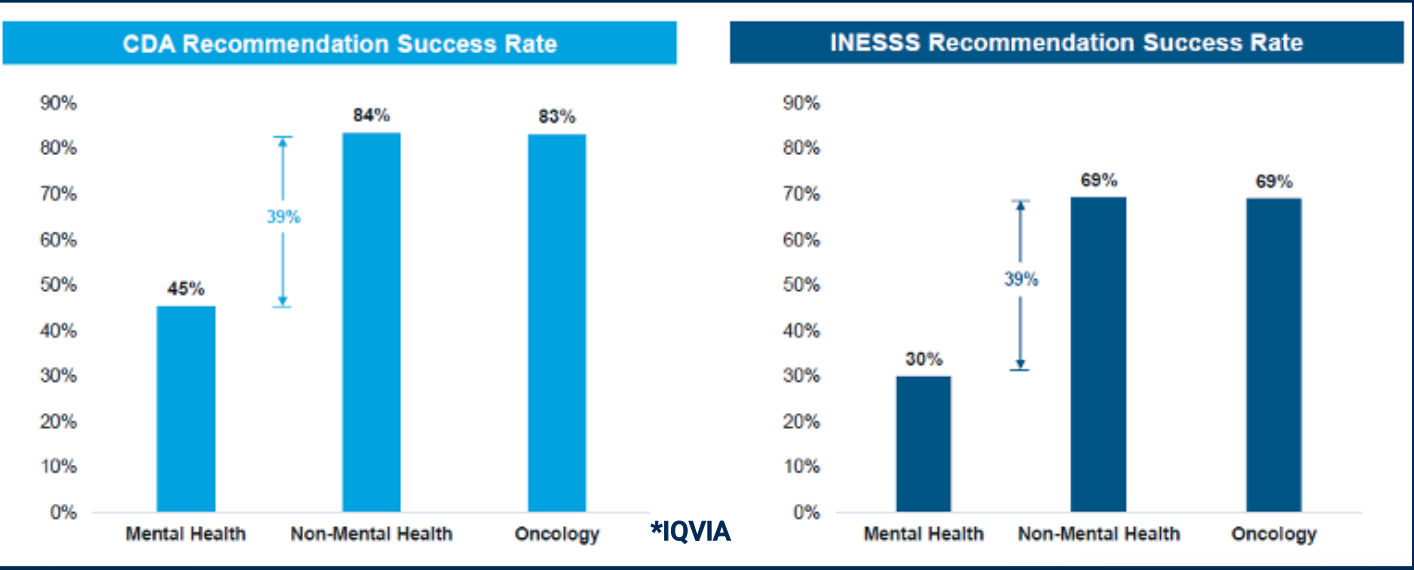
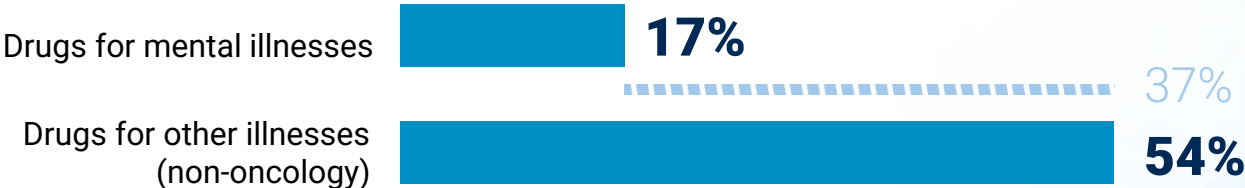
Fred Horne,
Former Alberta
Minister of Health
Senior Advisor,
3Sixty Public Affairs Inc.



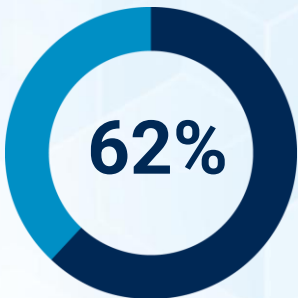
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CDA-AMC Positive Recommendations on Psychiatric Medications

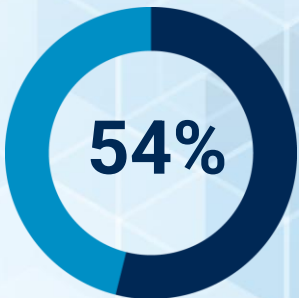
CDA Recommendation Success Rate



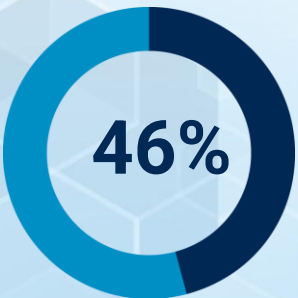
46-62% of psychiatric drugs not publicly reimbursed in any of Canada’s four most populous provinces



not funded
Quebec



not funded
BC or AB



not funded
Ontario

Access to Medications Working Group Panel Overview

Situation

- Higher rate of negative assessments from CDA-AMC & INESSS on psychiatric medications
- Assessing value of psychiatric drugs is complex & may include **biases and blind spots**

Panel Objectives

- Provide background on MDSC Working Group & how they chose to address the issue:
- Present **Value Consideration Framework** on clinically meaningful endpoints in MI that can help close the equity gap in access to psychiatric medications
- Interactive **case study**

The Panel



Fred Horne

Former Provincial Minister of Health

- Case for change



Aimée Tran Ba Huy

PWLE

- Proposed solution – Value Consideration Framework



Graham Statt

Former Provincial Payer

- Societal perspective guidance



Adam Haynes

Pharmaceutical Industry

- PROS & addressing uncertainty



Dr. Pierre Blier

Psychiatric Clinician

- In a decision-maker's shoes case study





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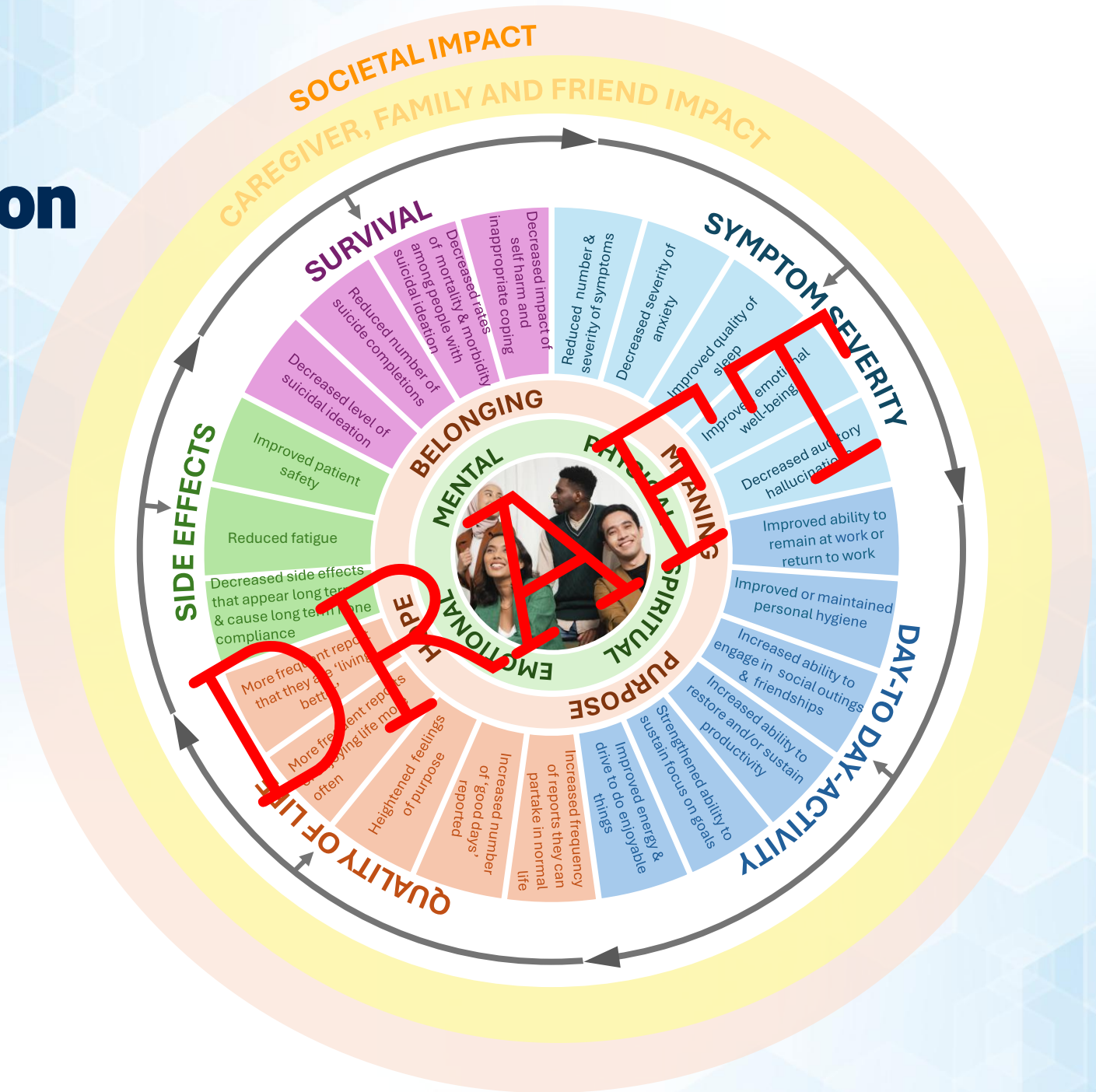


Aimée Tran Ba Huy,
PWLE

**National Project Coordinator,
Mood Disorders Society
of Canada**

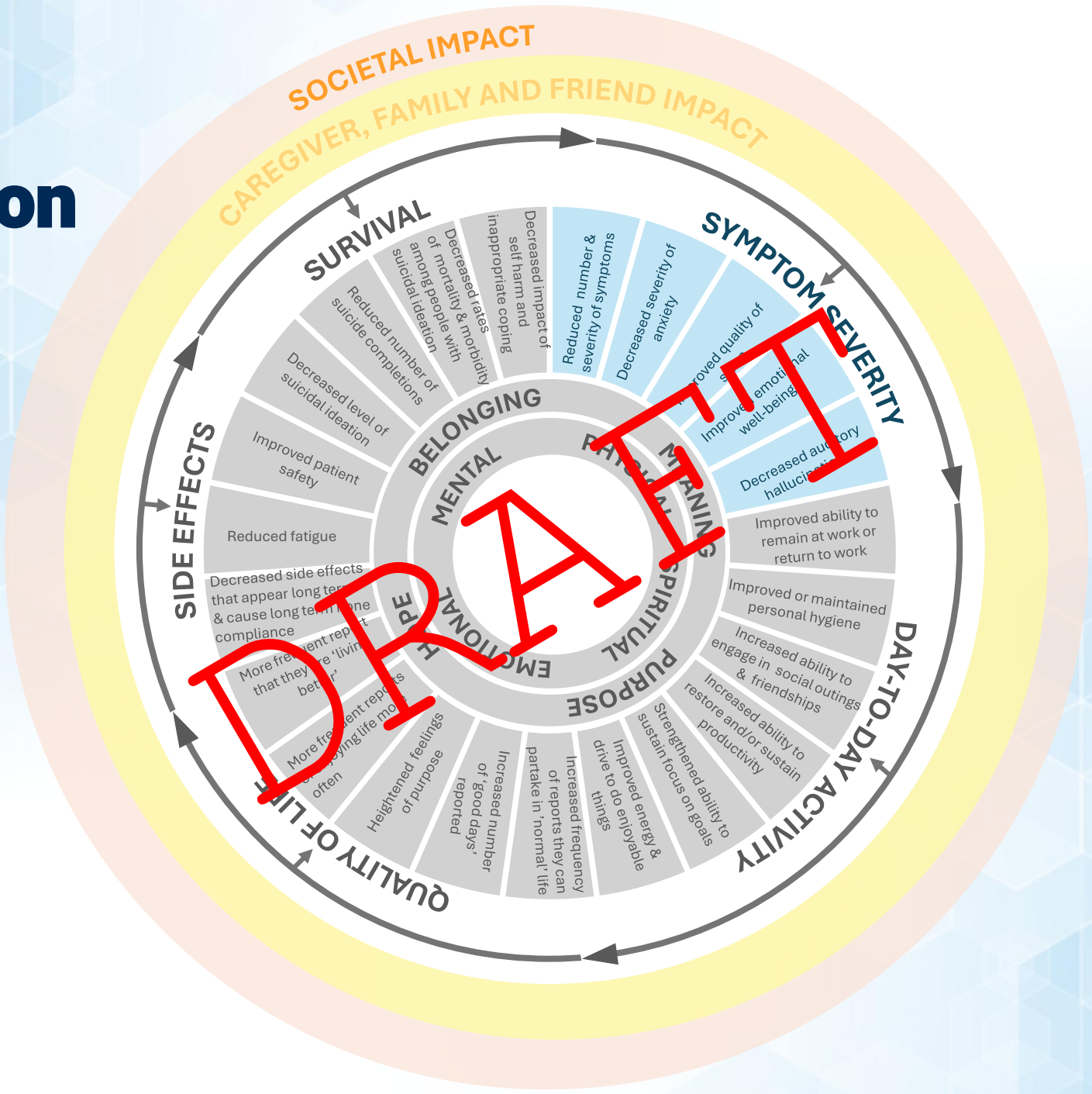


Value Consideration Framework



Value Consideration Framework

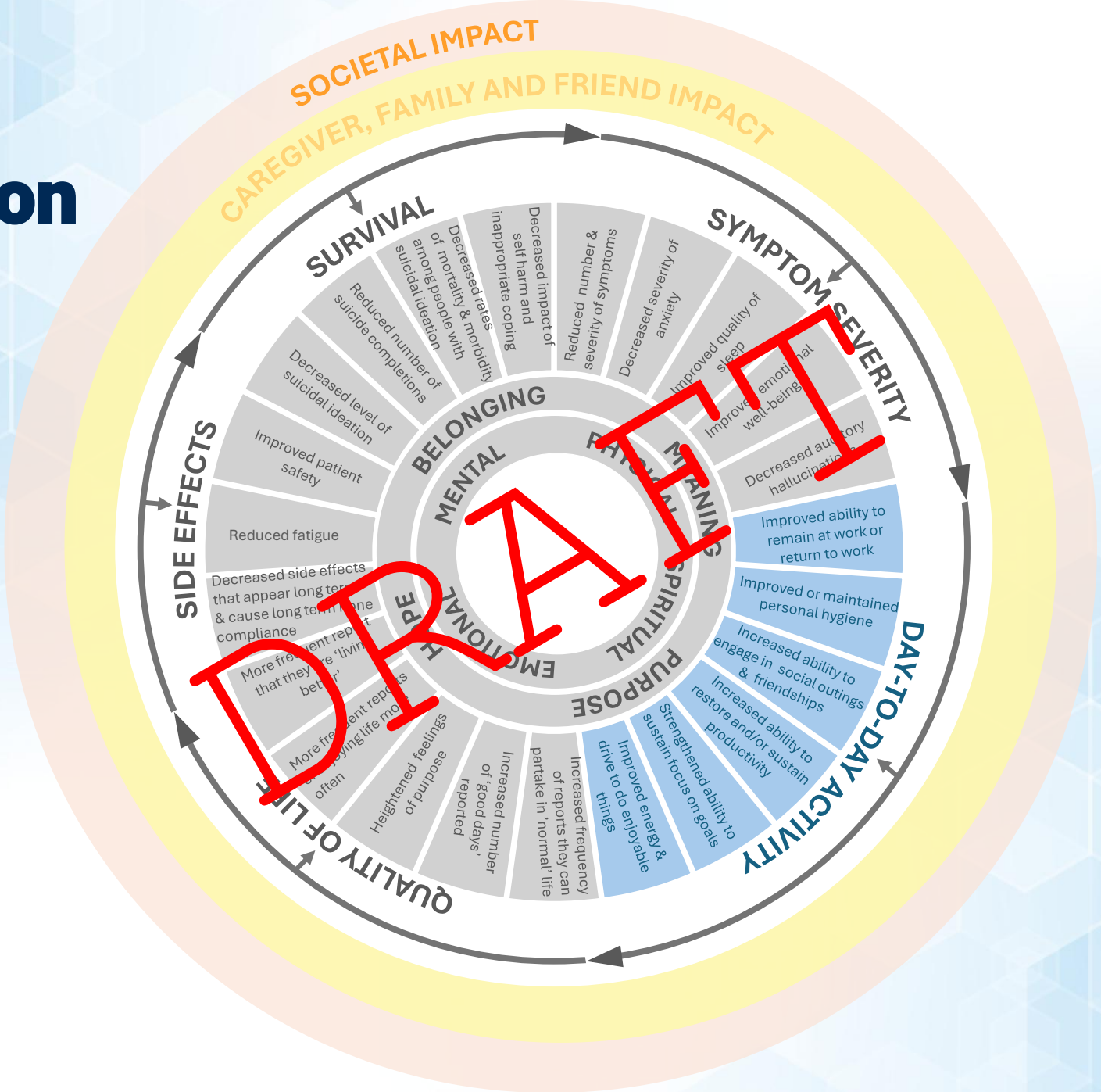
How a Patient Feels



How a Patient Feels (Symptom Severity)
Reduced number and severity of symptoms
Decreased severity of anxiety
Improved quality of sleep
Improved emotional well-being
Decreased auditory hallucinations
Improved concentration and focus
Decreased frequency of acute symptoms /symptom improvement
Improved mood
Fewer somatic symptoms
Improved adaptive behaviour
Better cognition
Decreased impact the person's symptoms of mental illness have on their caregiver
Increased appetite regulation
Improved symptoms reported by caregiver

Value Consideration Framework

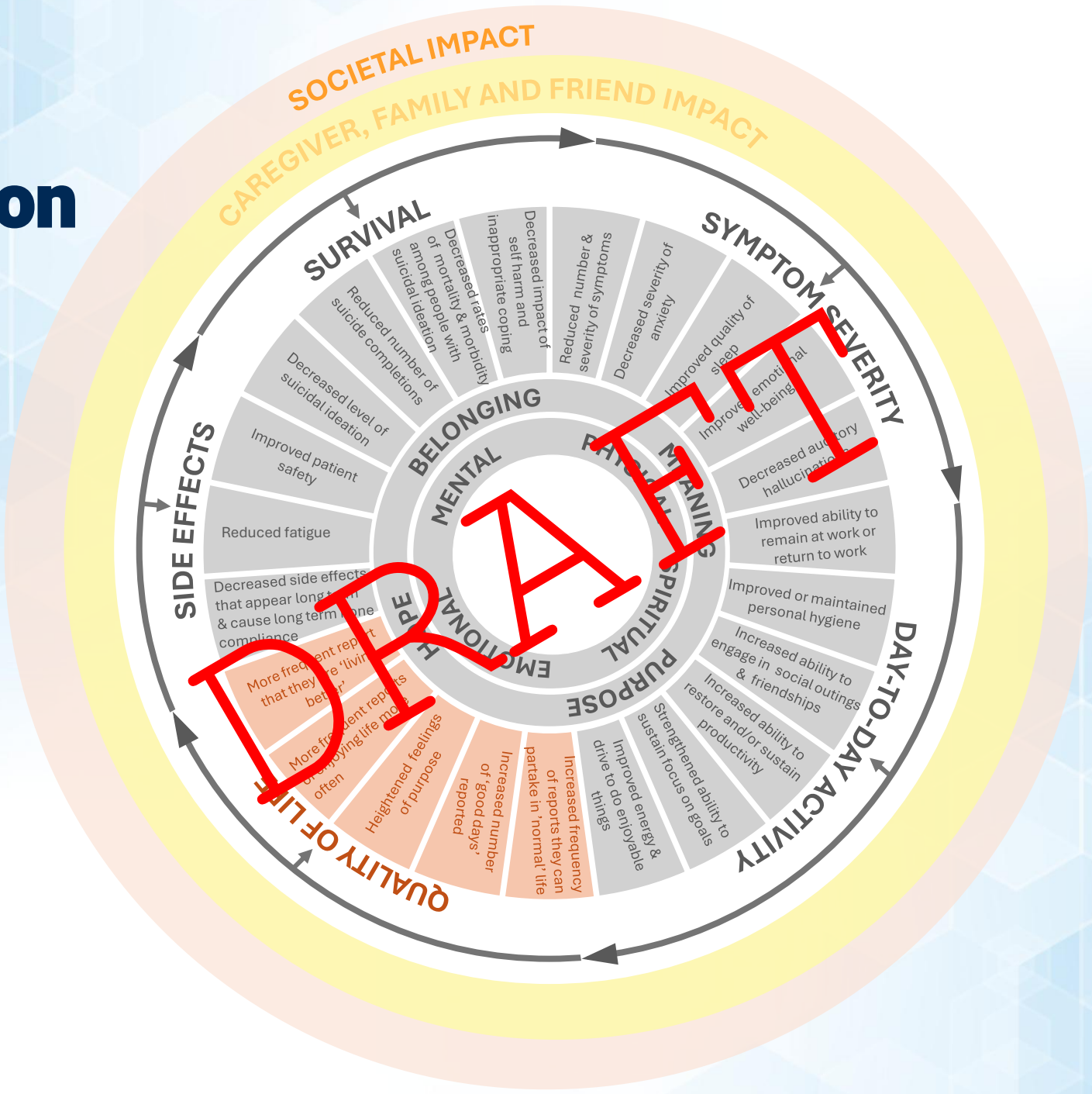
How a Patient Functions



How a Patient Functions (Day-to-day Activity)
Improved ability to remain at work or return to work without consequences
Improved or maintained personal hygiene
Increased ability to engage in social outings and friendships
Increased ability to restore and/or sustain productivity
Strengthened ability to sustain focus on goals
Improved energy and drive to do enjoyable things
Reduced workplace absenteeism
Increased ability to return to work after disability leave
Less workplace presenteeism
Increased ability to leave the house
Increased healthy habits
Improved ability to carry on a conversation without distraction
Decreased impact on the caregiver's ability to undertake daily activities
Less impact on family members

Value Consideration Framework

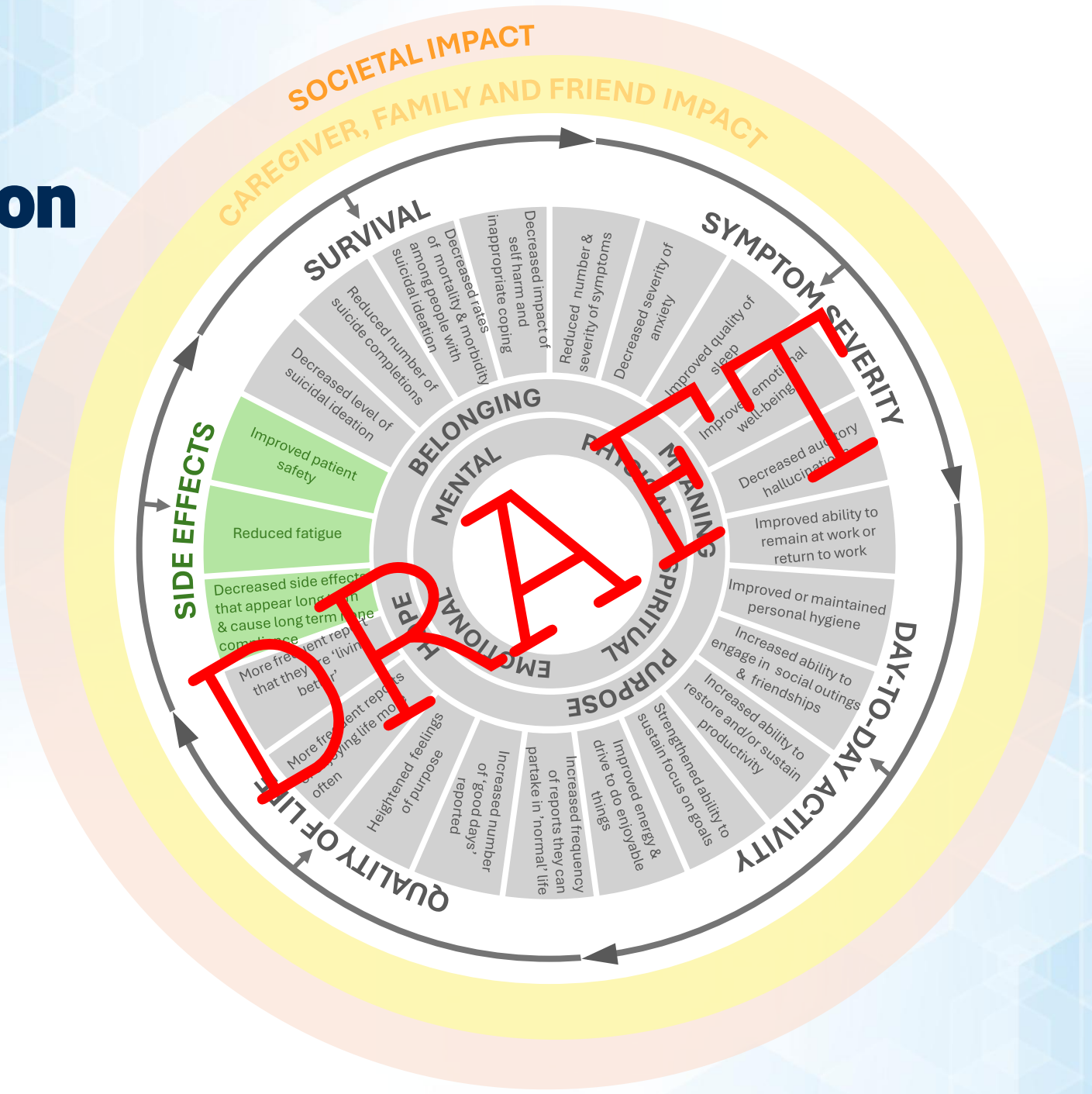
A Patient's Overall Wellbeing



A Patient's Overall Wellbeing (Quality of Life)
Increased frequency of reports they can partake in 'normal' life
Increased number of 'good days' reported
Heightened feelings of purpose
More frequent reports of enjoying life more often
More frequent reports they are 'living better'
Reduced feelings of shame
Heightened frequency of experiencing joy more often
Increased reports of feeling loved more often
Increased feelings of being valued by society
Reduced impact of the social determinants of health
Improved well-being reported by family & friends
Increased impact on the caregiver's overall well-being
Strengthened quality of relationships
Improved overall well-being of their person reported by the caregiver

Value Consideration Framework

Patient Adverse Events

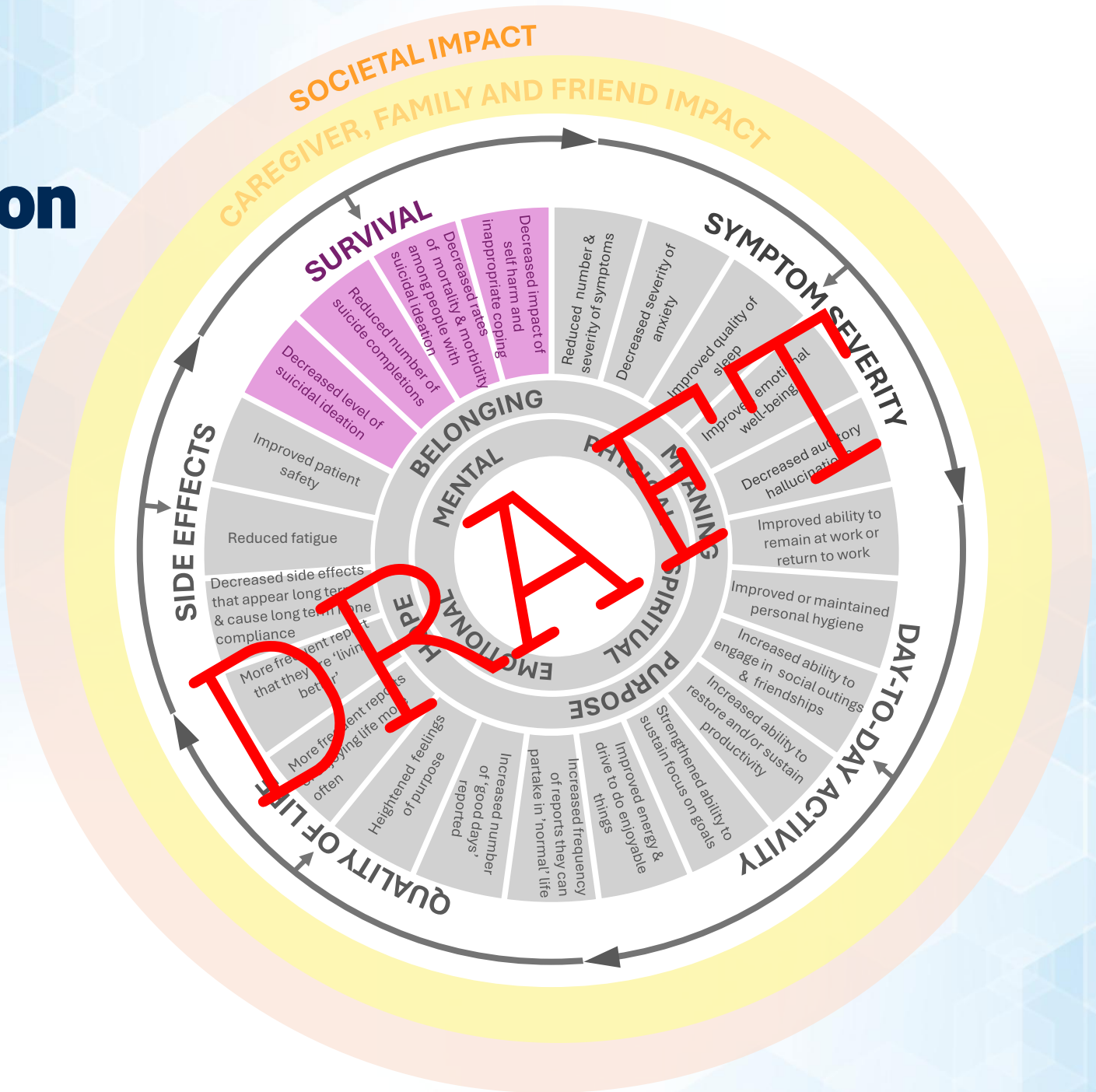


Patient Adverse Events (Side-effects)
Decreased side effects that appear longer term & cause longer term non-compliance
Reduced fatigue
Improved patient safety
Decreased side effects that appear rapidly & cause treatment discontinuation
Diminished side effect burden associated with therapies
Decreased weight gain
Reduced level of patient drop-off rates (do not fill or re-fill prescription)
Improved sexual function
Increased tolerability
Diminished side effect burden reported by the caregiver
Decreased impact on the caregiver from helping their person manage
Decreased number of non-responders



Value Consideration Framework

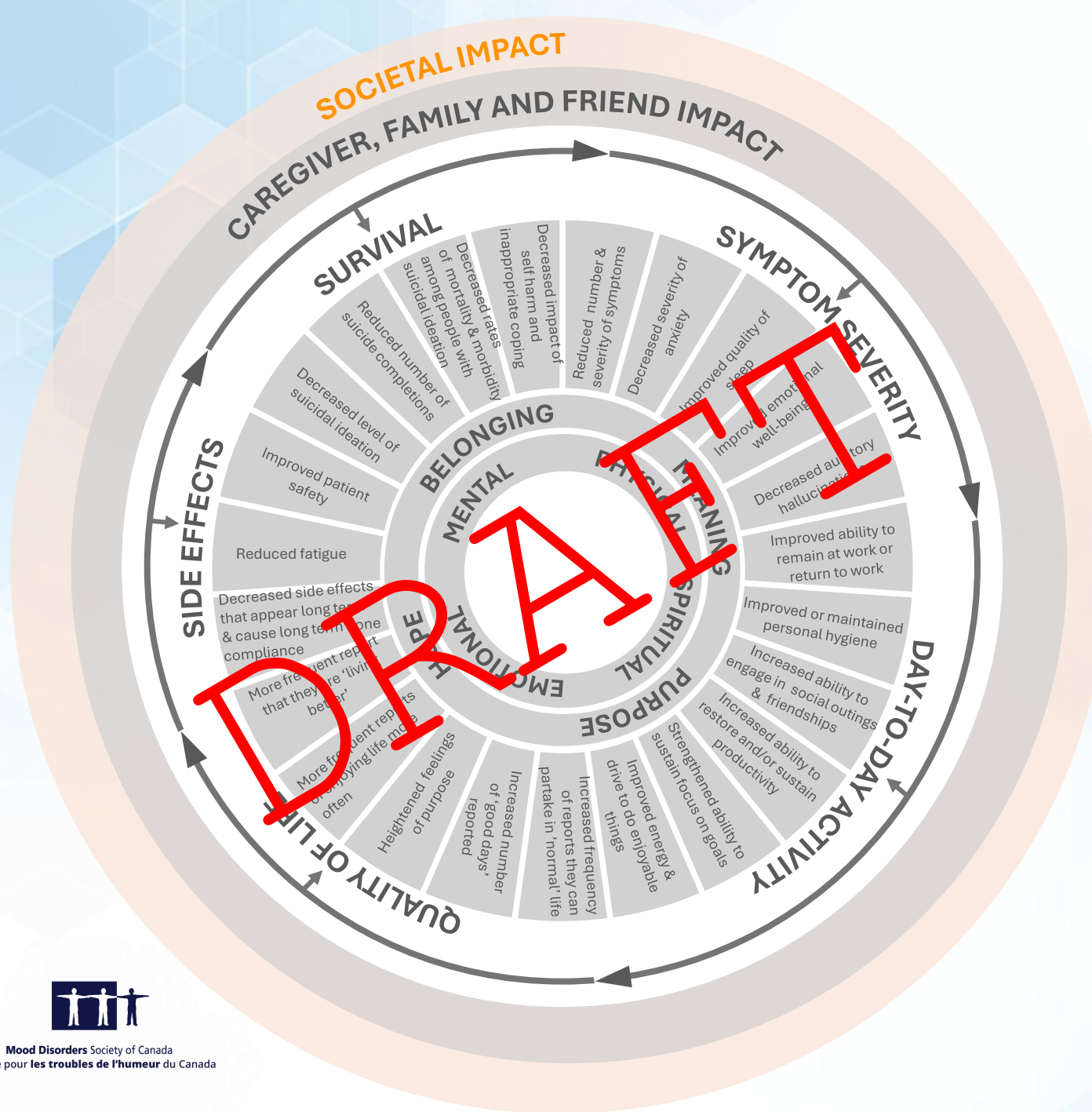
Patient's Lifespan



Patient's Lifespan (Survival)
Decreased level of suicidal ideation
Reduced number of suicide completions
Decreased rates of mortality & morbidity among people with suicidal ideation
Decreased impact of self-harm & inappropriate coping
Improved behaviour modification (self-harm reduction)
Decreased impact on friends, family & community from suicide
Reduced cost to society from suicide attempts/completions
Decreased impact on caregivers from suicide ideation, attempts or completion
Decreased impact/loss to society from suicide attempts & completions

Value Consideration Framework

Societal Impact



Health System Indicators	Significant Health Equity Considerations
Decreased number of hospital admissions	More timely access to quality healthcare
Decreased frequency of emergency room visits	Improvement in employment & job security
Reduced avoidable healthcare service costs	Greater income security & poverty reduction
Reduced frequency of medical consultations	More stable & affordable housing
Decreased inpatient length of stay in the hospital	Less childhood adversity
Fewer disability claims	Increased social connection & inclusion
	Less involvement with the criminal justice system
	Improved literacy & education
	More sufficient, safe & nutritious food
	Greater freedom from discrimination





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Graham Statt,
**Former Public Payer/
Vice-Chair pCPA**
Senior Advisor, Santis Health



Understanding Public Payers

Given fiscal sustainability challenges, there may be some inertia

Some **areas that resonate** from the **'lens' of the public payer**:



Areas of disease severity



Particular kinds of sensitive political items – i.e., pediatric cancer, rare disease



Significant unmet need



Size of the patient population (if very small, and a new commercial therapy maybe Special Auth.)



To some extent, productivity where it can be calculated and quantified



To some extent, convenience for patients where there are travel barriers/rural and remote



Convenience of different formulations where those also help the health system as a whole



Adherence



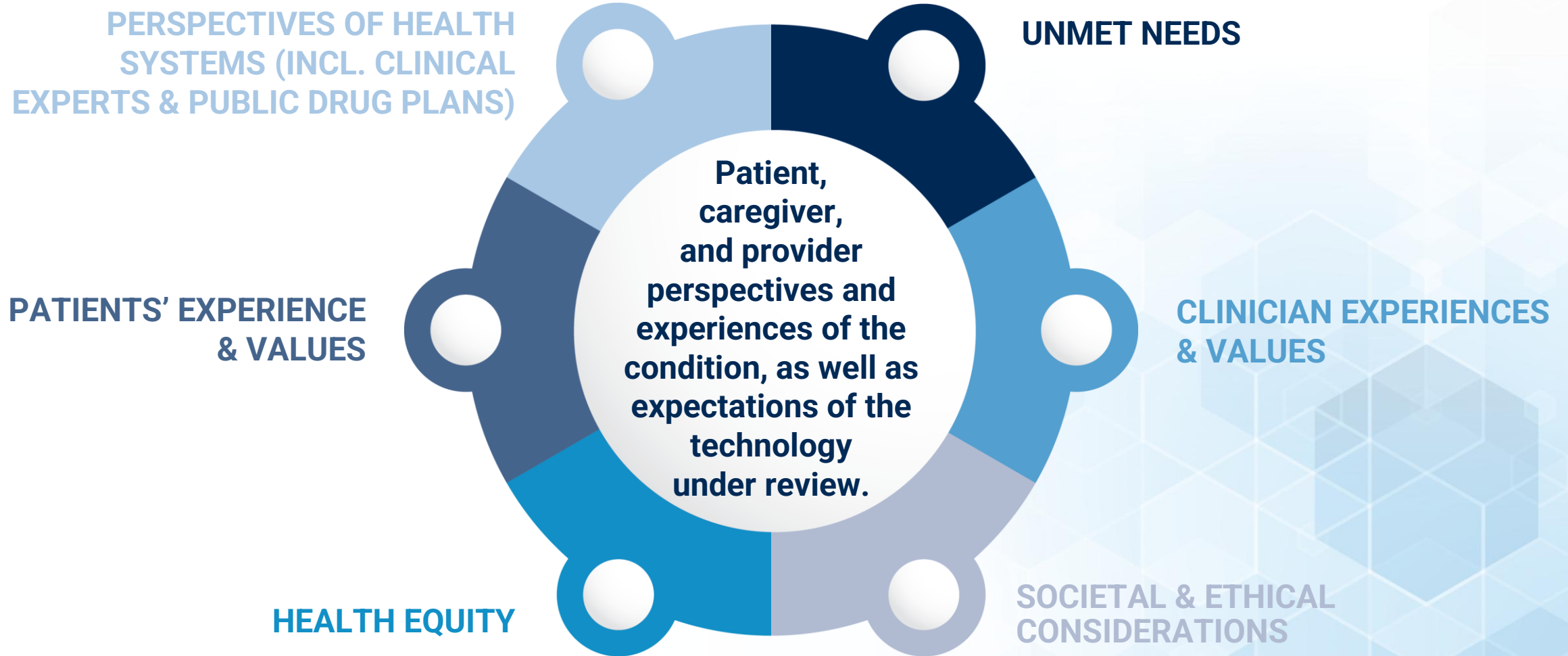
Reduction in 'casualty services' where those are quantifiable

VERY interested in hard data and HTA advice

- It is the only way to bring consistency to when and how to say 'no' to a treatment (equity and fairness)
- Want to stay aligned with other jurisdictions to ensure the pricing system remains intact

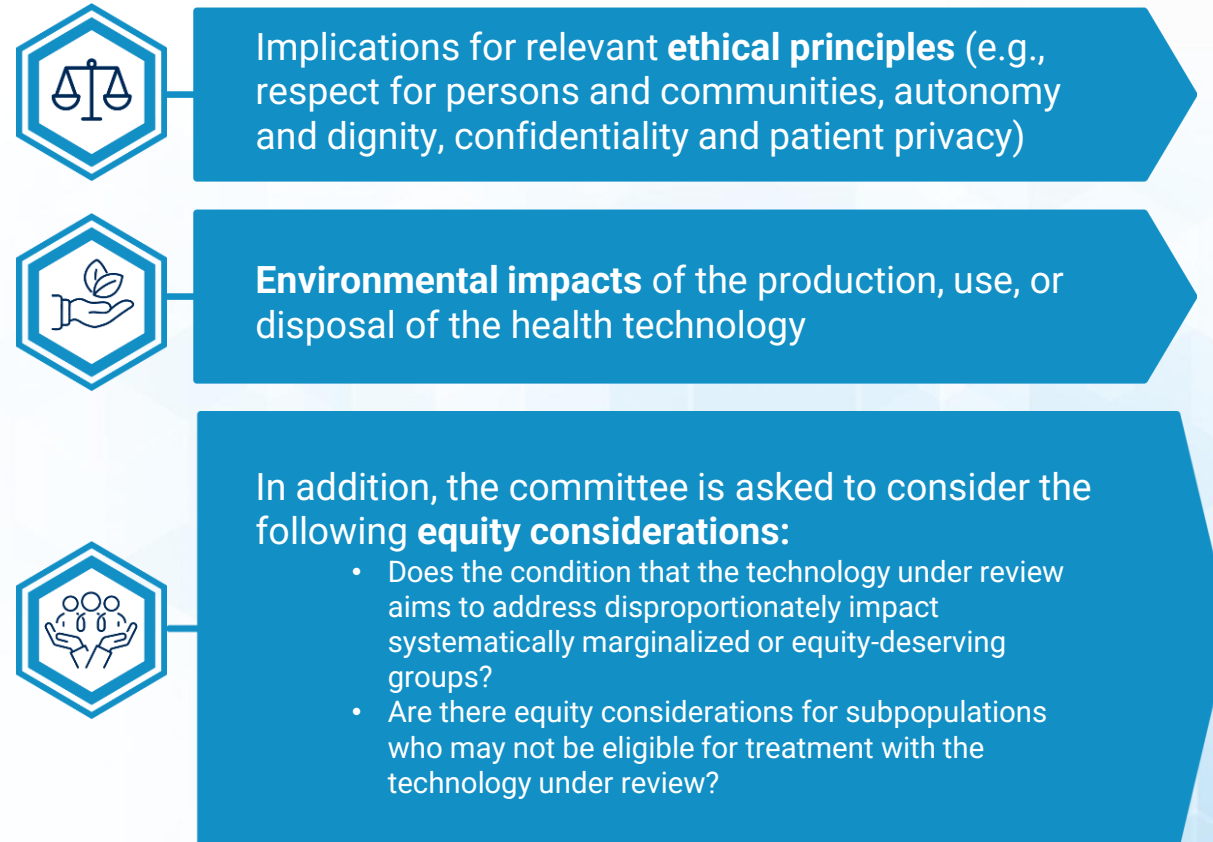
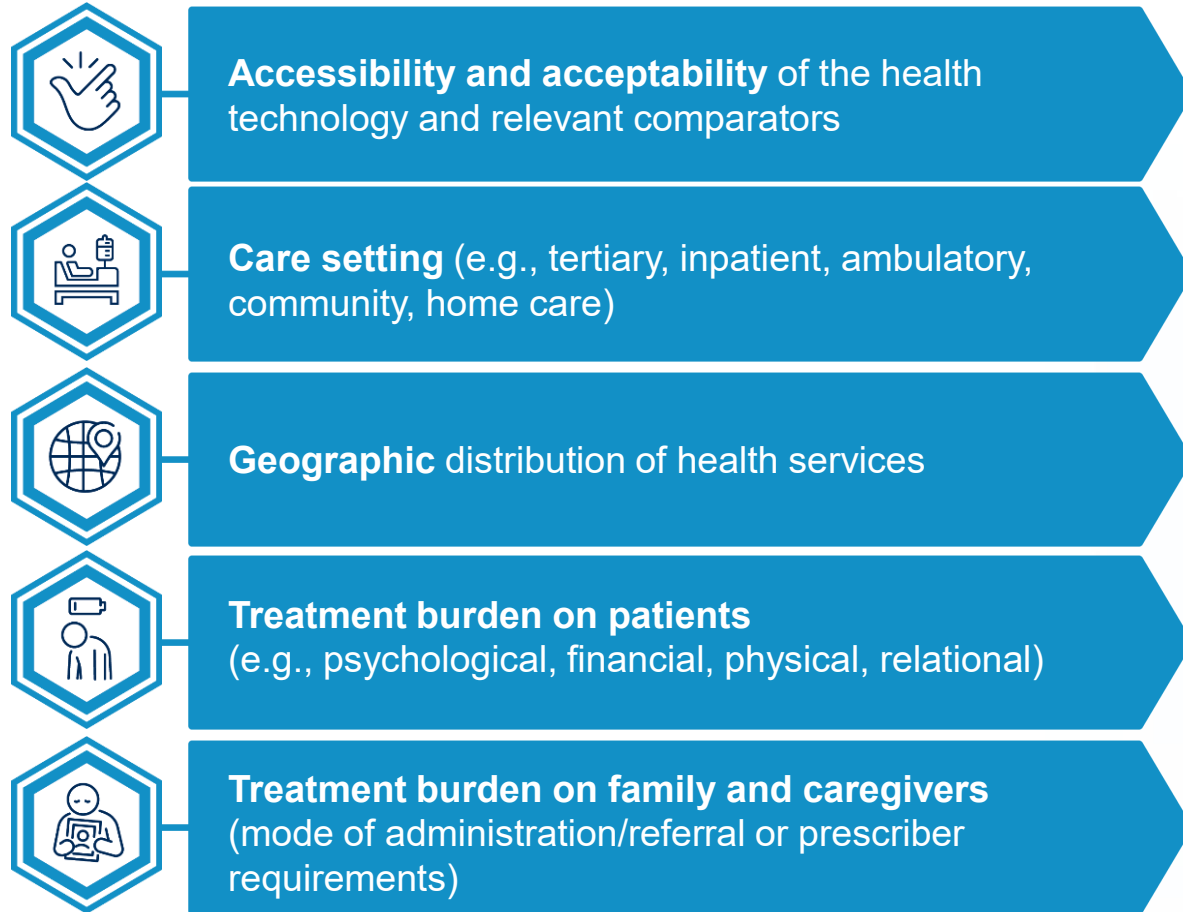
From the CDA-AMC Deliberative Framework

Value Considerations



From the CDA-AMC Deliberative Framework

Value Considerations



CDA-AMC Societal Perspective Pilot

Pilot provides insight into the direction CDA-AMC might be heading... mental health could be included

Expands the economic model submitted by a drug sponsor (manufacturer)

If societal perspective is used in an economic model, it expands considerations to include both:

1. health care payer costs and
2. associated costs that fall outside the health care system

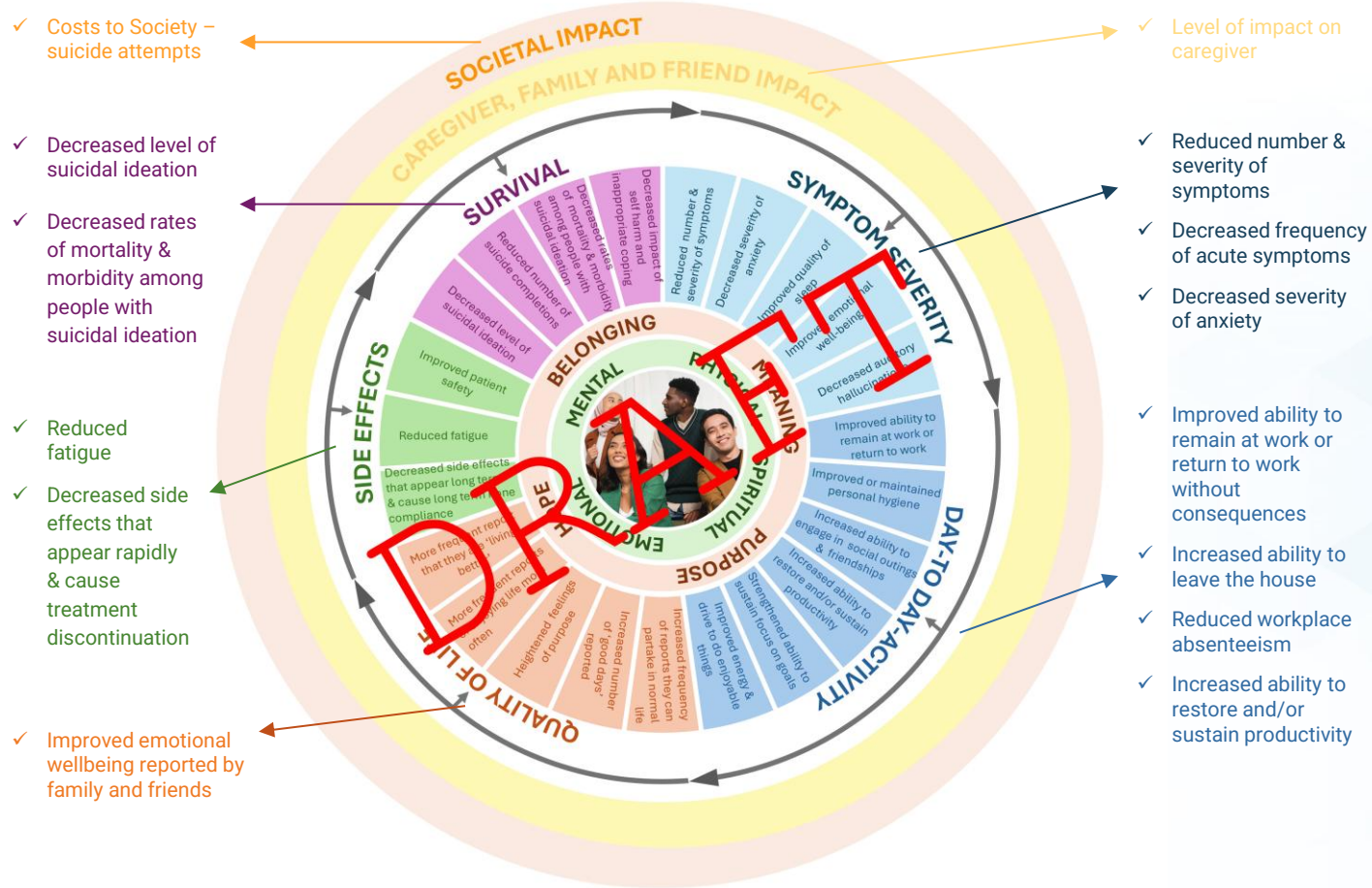
Examples of “societal costs” include patients taking time off for treatment, productivity costs to society from patients being unable to work and costs to other government sectors



Current eligibility:

Those eligible for the 'complex' review process including cell and gene, cancer, first in class drugs, those under expedited review, or undefined place in therapy.

Value Consideration List from our Framework (Broadly)



Societal Costs - Productivity

Consider the economic value of increased productivity through decreased symptom management including fatigue and anxiety

Societal Costs - Caregiver Burden

Give weight to the physical, economic and mental burden on caregivers including their own productivity within society

Societal Costs – Broader Sector Services

Value the benefits of increased adherence to beneficial treatment, and reduced interaction with emergency services

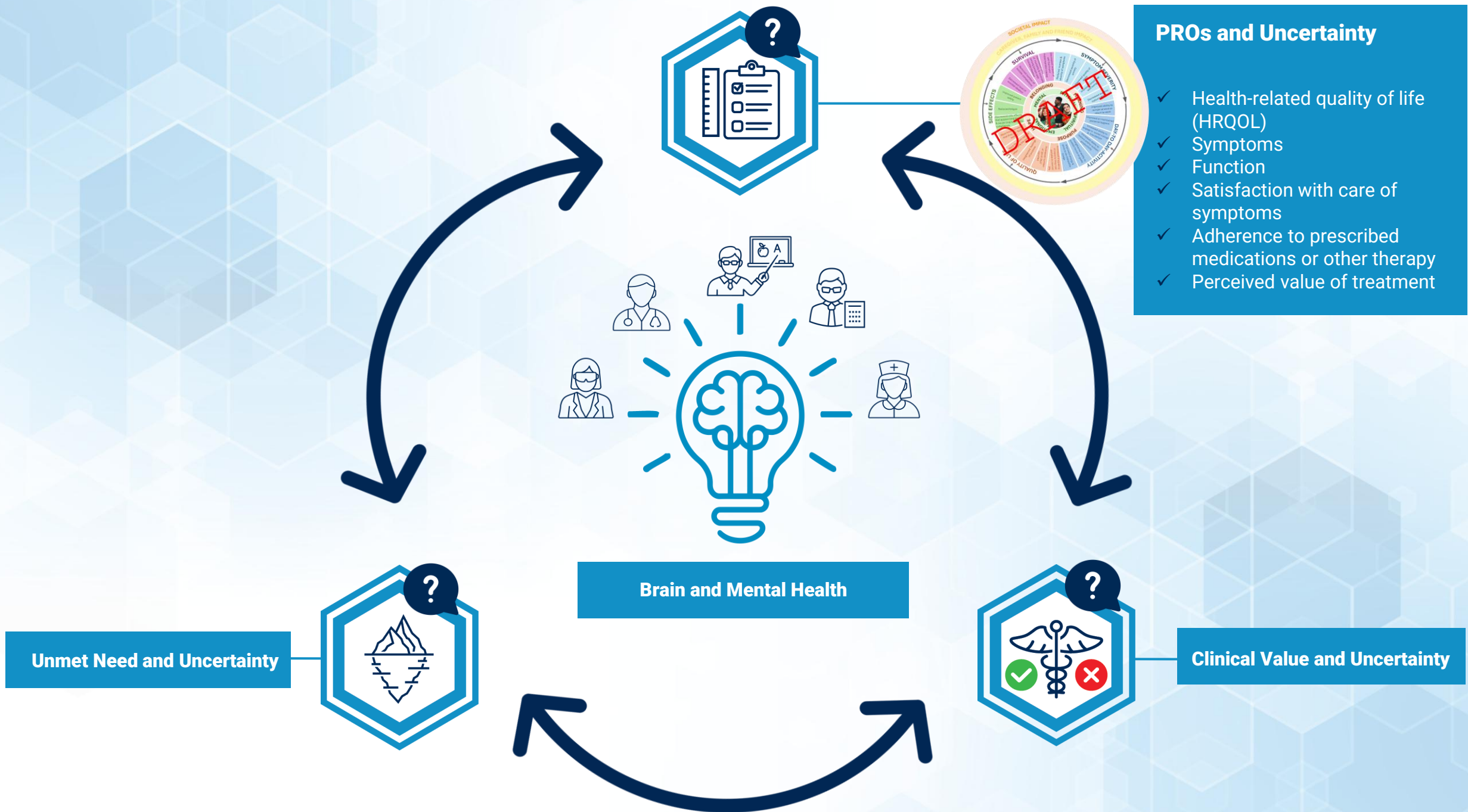


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Adam Haynes,
Pharmaceutical Industry
Associate Director, Market Access,
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Dr. Pierre Blier,
Psychiatric Physician
Professor, Dept. of Psychiatry &
Cellular and Molecular Medicine,
University of Ottawa





Bipolar 1

Meet Darius ...

- 66-year-old senior
- Retired: ex-Director from Lululemon; now volunteer Chair of Board for national charity; volunteer Program Lead for food bank in local community feeding 10,000 weekly
- In addition to Bipolar 1, has diabetes, heart disease; has been trying to manage weight to not exacerbate his comorbidities
- 59-year-old wife is main caregiver whom he relies on heavily to manage Bipolar and comorbidities; had to stop working to care for him
- Current medications keep him mostly stable, but tried 8 others over the years and had to discontinue them due to tolerability – weight gain side effect worsened his diabetes & heart disease; medication sedation side effect makes it hard to stay alert at previous role and volunteer roles now
- New medication available with fewer side effects – causes less weight gain & sedation – but now that he's retired, relies on public drug plan, which doesn't cover the medication

CDA Deliberative Framework – Drug Y Bipolar (Without Value Consideration Framework)

 Beneficial Considerations (+) 	Clinical Value Significantly improved side effect & safety profiles (lower weight gain [risk of diabetes, cholesterol impact]; reduced sedation & cognitive dulling; better tolerability [lower discontinuation rate])	Unmet Clinical Needs 2 Patient Organization submissions noted high unmet need for drugs with fewer side effects & reduction in caregiver burden, PROs collected are most important	Economic Considerations	Societal & Ethical Considerations Complex review (due to safety considerations & long-term use)	Impact on Health System Expected utilization: reduced health system costs for co-morbidities (obesity, diabetes, etc.)
Detrimental Considerations (-) 	Same class as existing mood stabilizers Similar efficacy to SOC (non-inferior, but not superior) PRO: HRQoL collected (HTA deemed exploratory & could not draw definitive conclusions)	HTA deemed minimal unmet need because multiple treatments exist & considered effective (even though come with weight gain, sedation, tolerability challenges)	Medium patient cost, per year ICER >\$50K threshold (\$75K per QALY) Medium incremental drug budget impact	BUT no societal perspective (although high caregiver burden & productivity impacts) Ethics review (deemed insufficiently detailed, despite high caregiver burden) No live PWLE (couldn't find any)	



Beneficial Considerations (+)



Clinical Value

Significantly improved side effect & safety profiles (lower weight gain [risk of diabetes, cholesterol impact]; reduced sedation & cognitive dulling; better tolerability [lower discontinuation rate])

Symptoms: Improved emotional wellbeing

Symptoms: Better cognition

QoL: Increased frequency of reports they can partake in 'normal life'

Day to day activity: Increased healthy habits

Unmet Clinical Needs

2 Patient Organization submissions noted high unmet need for drugs with fewer side effects & reduction in caregiver burden, PROs collected are most important

Side Effects: Decreased side effects that appear longer term & cause longer term non-compliance

Side Effects: Decreased weight gain

Side Effects: Increased tolerability

Economic Considerations

Day-to-day activity: Improved ability to remain at work or return to work without consequences

Day to day activity: Increased ability to restore and/or sustain productivity

Survival: Reduced number of suicidal completions

Survival: Decreased cost to society from suicide completions/attempts

Societal & Ethical Considerations

Complex review (due to safety considerations & long-term use)

Caregiver: Decreased impact on caregiver's ability to undertake daily activities

Caregiver: Decreased impact on caregivers from suicide ideation, attempts or completion

Caregiver: Decreased impact on the caregiver from helping the person manage

QoL: Reduced feelings of shame

Survival: Decreased level of suicidal ideation

Impact on Health System

Expected utilization: reduced health system costs for co-morbidities (obesity, diabetes, etc.)

Societal: Decreased number of hospital admissions

Societal: Reduced frequency of medical consultations

Societal: Decreased inpatient length of stay in hospital

Detrimental Considerations (-)



Same class as existing mood stabilizers

Similar efficacy to SOC (non-inferior, but not superior)

PRO: HRQoL collected (HTA deemed exploratory & could not draw definitive conclusions)

HTA deemed minimal unmet need because multiple treatments exist & considered effective (even though come with weight gain, sedation, tolerability challenges)

Medium patient cost, per year

ICER >\$50K threshold (\$75K per QALY)

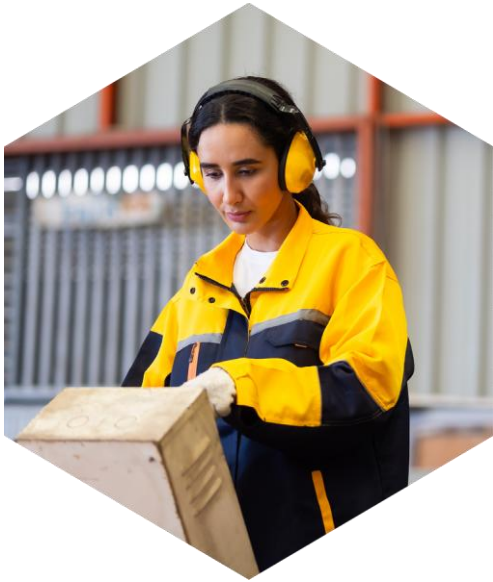
Medium incremental drug budget impact

BUT no societal perspective (although high caregiver burden & productivity impacts)

Ethics review (deemed insufficiently detailed, despite high caregiver burden)

No live PWLE (couldn't find any)

M



Chronic Insomnia

Meet Claudette ...

- 38-year-old single mother **juggling joint custody of kids** with ex-husband
- Works as **equipment operator** (2 p/t jobs)
- Adding to depression and anxiety, now **experiencing insomnia** - when she can't sleep, she can't focus to safely operate equipment at work
- **Sick days piling up at work - calling on her mother too often** to help with appointments, kid activities and everything else she is trying to balance
- Because she's p/t doesn't have workplace benefits so relies on **public drug plan ... but they don't cover the insomnia medicine her doctor is recommending to help**
- Ex-husband's workplace drug plan DOES have it but fully disentangling from his private drug plan would mean **losing her treatment** and all hope of getting by
- Worse yet, she read article that says government decided the medicine costs too much to add to public plan based on **strict clinical data alone**

CDA Deliberative Framework – Drug X Chronic Insomnia

(Without Value Consideration Framework)



**Beneficial
Considerations
(+)**



Clinical Value

New MOA

Added clinical value statistically significant improvements: shorter time to sleep & total sleep time in minutes (**HTA deemed uncertain**)

Improved side effects & safety: no overdoses; no dependency

Unmet Clinical Needs

3 Patient Organization submissions noted **high unmet need for safe drugs** (vis a vis harms), side effects, and improved next day function, and long-term effectiveness that **improves workplace absenteeism and presenteeism**, PROs collected are most important

Economic Considerations

Medium per patient costs/year

ICER >\$50K threshold (\$100Kper QALY)

High incremental drug budget impact

Societal & Ethical Considerations

Standard review = no ethics review (but perceived improvement in burden on family & caregivers)

No societal perspective (although high productivity impacts)

No live PWLE at Committee

Impact on Health System

Expected utilization assumes **less use of older sleep meds (with harms/safety concerns)** if drug X available

**Detrimental
Considerations
(-)**



PRO: HRQoL collected (**HTA deemed exploratory & could not draw definitive conclusions**)

HTA deemed minimal unmet need because treatments exist (although come with risk of dependency)

Medium per patient costs/year

ICER >\$50K threshold (\$100Kper QALY)

High incremental drug budget impact

Standard review = no ethics review (but perceived improvement in burden on family & caregivers)

No societal perspective (although high productivity impacts)

No live PWLE at Committee



Beneficial Considerations (+)



Detrimental Considerations (-)



Clinical Value

New MOA

Added clinical value statistically significant improvements: shorter time to sleep & total sleep time in minutes (**HTA deemed uncertain**)

Improved side effects & safety: no overdoses; no dependency
QoL: Increased number of good days reported

Symptoms: Improved quality of sleep

Day-to-day activity: Improved energy & drive to do enjoyable things

PRO: HRQoL collected (**HTA deemed exploratory & could not draw definitive conclusions**)

Unmet Clinical Needs

3 Patient Organization submissions noted **high unmet need for safe drugs** (vis a vis harms), side effects, and improved next day function, and long-term effectiveness that **improves workplace absenteeism and presenteeism**, PROs collected are most important

Side Effects: Reduced fatigue

Day-to-day activity: Improved ability to remain at work or return to work without consequences

Day to day activity: Increased ability to restore and/or sustain productivity

HTA deemed minimal unmet need because treatments exist (although come with risk of dependency)

Economic Considerations

Survival: Decreased impact of self-harm & inappropriate coping

Medium per patient costs/year

ICER >\$50K threshold (\$100Kper QALY)

High incremental drug budget impact

Societal & Ethical Considerations

Societal: Reduction in workplace presenteeism & absenteeism

Caregiver: Decreased impact on the caregiver from helping their person manage

QoL: Reduced impact of the societal determinants of health

Symptoms: Better cognition

Day-to-day activity: Strengthened ability to sustain focus on goals

Standard review = no ethics review (but perceived improvement in burden on family & caregivers)

No societal perspective (although high productivity impacts)

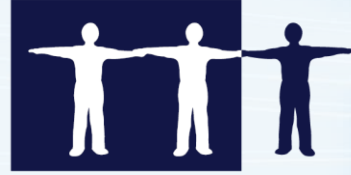
No live PWLE at Committee

Impact on Health System

Expected utilization assumes **less use of older sleep meds (with harms/safety concerns)** if drug X available

Societal: Fewer disability claims

Societal: Reduced avoidable healthcare service costs



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Thank You & Q&A

More information can be found at:



[ACCESSTOMEDICATION.MDSC.CA](https://www.accessmedication.mdsc.ca)

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