Extended-Release Opioid Agonists and Antagonist Medications for Addiction Treatment (MAT) in Patients with Opioid Use Disorder: Effectiveness and Value

Questions for Deliberation and Voting: November 8, 2018 Public Meeting

These questions are intended for the deliberation of the New England CEPAC voting body at the public meeting.

Patient Population for all questions: Patients 16 years or older with opioid use disorder, who are being considered for MAT.

Clinical Evidence

1. Is the evidence adequate to demonstrate that the net health benefit of the buprenorphine subcutaneous extended-release injection Sublocade™ (Indivior) is superior to that provided by transmucosal formulations of buprenorphine/naloxone?

   Yes No

2. Is the evidence adequate to demonstrate that the net health benefit of the buprenorphine subcutaneous extended-release injection CAM2038 (Braeburn) is superior to that provided by transmucosal formulations of buprenorphine/naloxone?

   Yes No

3. Is the evidence adequate to demonstrate that the net health benefit of buprenorphine implant Probuphine® (Titan Pharmaceuticals Inc.) is superior to that provided by transmucosal formulations of buprenorphine/naloxone?

   Yes No

4. Is the evidence adequate to demonstrate that the net health benefit of naltrexone intramuscular extended-release injection Vivitrol® (Alkermes) is superior to that provided by transmucosal formulations of buprenorphine/naloxone?

   Yes No

5. Is the evidence adequate to distinguish the net health benefit among the following interventions:
    - the two buprenorphine subcutaneous extended-release injections (Sublocade and CAM2038)
    - the buprenorphine implant (Probuphine)
    - naltrexone intramuscular extended-release injection (Vivitrol)

Yes No

Potential Other Benefits and Contextual Considerations

6. Does treating patients with one of the extended-release interventions (CAM2038, Sublocade, Probuphine, or Vivitrol) offer one or more of the following potential "other benefits" vs transmucosal formulations of buprenorphine/naloxone? (select all that apply)
    a. **CAM2038 and Sublocade** offer reduced complexity that will significantly improve patient outcomes.
    b. **Probuphine** offers reduced complexity that will significantly improve patient outcomes.
    c. **Vivitrol** offers reduced complexity that will significantly improve patient outcomes.
    d. These interventions will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
    e. These interventions will significantly reduce caregiver or broader family burden.
    f. **CAM2038 and Sublocade** offer a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
    g. **Probuphine** offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
    h. **Vivitrol** offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
    i. These interventions will have a significant impact on improving patients' ability to return to work and/or their overall productivity.
    j. There are other important benefits or disadvantages that should have an important role in judgments of the value of these interventions: _____

7. Are any of the following contextual considerations important in assessing the long-term value for money of the extended-release interventions (CAM2038, Sublocade, Probuphine, or Vivitrol)? (select all that apply)
    a. These interventions are intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
    b. These interventions are intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
    c. These interventions are the first to offer any improvement for patients with this condition.
    d. There is significant uncertainty about the long-term risk of serious side effects of **CAM2038.**
    e. There is significant uncertainty about the long-term risk of serious side effects of **Sublocade.**
    f. There is significant uncertainty about the long-term risk of serious side effects of **Probuphine**.
    g. There is significant uncertainty about the long-term risk of serious side effects of **Vivitrol**.
    h. There is significant uncertainty about the magnitude or durability of the long-term benefits of **CAM2038.**
    i. There is significant uncertainty about the magnitude or durability of the long-term benefits of **Sublocade**.
    j. There is significant uncertainty about the magnitude or durability of the long-term benefits of **Probuphine.**
    k. There is significant uncertainty about the magnitude or durability of the long-term benefits of **Vivitrol.**
    l. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

Long-Term Value for Money

As described in ICER's recent update to its value assessment framework, questions on "long-term value for money" are subject to a value vote only when incremental cost-effectiveness ratios for the interventions of interest are between $50,000 and $175,000 per QALY in the primary "base case" analysis. As shown in the Draft Evidence Report, the estimates for Probuphine, Sublocade, and Vivitrol exceed the higher end of the range. Consequently, all three interventions are deemed "low value" without formal voting by the public panel. CAM 2038 is not yet approved, and no price is available, so an incremental cost-effectiveness ratio could not be calculated; as a consequence, a value vote will not be taken.