



PARP Inhibitors for Ovarian Cancer: Effectiveness and Value

Draft Voting Questions for September 14, 2017 Public Meeting

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

Comparative Clinical Effectiveness

Olaparib

- 1) In patients with recurrent BRCA-mutated disease, is the evidence adequate to demonstrate that the net health benefit of treatment with olaparib is greater than that of treatment with standard chemotherapy?
Yes No
- 2) In patients with platinum-sensitive disease who are eligible for maintenance therapy, is the evidence adequate to demonstrate that the net health benefit of treatment with olaparib is greater than that of surveillance alone?
Yes No

Rucaparib

- 3) In patients with recurrent BRCA-mutated disease, is the evidence adequate to demonstrate that the net health benefit of treatment with rucaparib is greater than that of treatment with standard chemotherapy?
Yes No

Niraparib

- 4) In patients with platinum-sensitive, germline BRCA-mutated disease who are eligible for maintenance therapy, is the evidence adequate to demonstrate that the net health benefit of treatment with niraparib is greater than that of surveillance alone?
Yes No
- 5) In patients with platinum-sensitive disease who are eligible for maintenance therapy and do not have germline BRCA mutations, is the evidence adequate to demonstrate that the net health benefit of treatment with niraparib is greater than that of surveillance alone?
Yes No

Other Benefits

Olaparib

- 6) When compared to pegylated liposomal doxorubicin and carboplatin (PLD+C), does olaparib, for recurrent BRCA-mutated disease, offer one or more of the following “other benefits”? (yes, no, uncertain)
- This intervention provides significant direct patient health benefits that are not adequately captured by the QALY.
 - This intervention offers reduced complexity that will significantly improve patient outcomes.
 - This intervention will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
 - This intervention will significantly reduce caregiver or broader family burden.
 - This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients who have failed other available treatments.
 - This intervention will have a significant impact on improving return to work and/or overall productivity.
 - There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____
- 7) When compared to surveillance alone, does olaparib, for maintenance therapy in platinum-sensitive disease, offer one or more of the following “other benefits”? (yes, no, uncertain)
- This intervention provides significant direct patient health benefits that are not adequately captured by the QALY.
 - This intervention offers reduced complexity that will significantly improve patient outcomes.
 - This intervention will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
 - This intervention will significantly reduce caregiver or broader family burden.
 - This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients who have failed other available treatments.
 - This intervention will have a significant impact on improving return to work and/or overall productivity.
 - There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____

Rucaparib

- 8) When compared to PLD+C, does rucaparib, for recurrent BRCA-mutated disease, offer one or more of the following “other benefits”? (yes, no, uncertain)
- This intervention provides significant direct patient health benefits that are not adequately captured by the QALY.
 - This intervention offers reduced complexity that will significantly improve patient outcomes.
 - This intervention will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
 - This intervention will significantly reduce caregiver or broader family burden.
 - This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients who have failed other available treatments.
 - This intervention will have a significant impact on improving return to work and/or overall productivity.
 - There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____

Niraparib

- 9) When compared to surveillance alone, does niraparib, for maintenance therapy in platinum-sensitive disease, offer one or more of the following “other benefits”? (yes, no, uncertain)
- This intervention provides significant direct patient health benefits that are not adequately captured by the QALY.
 - This intervention offers reduced complexity that will significantly improve patient outcomes.
 - This intervention will reduce important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
 - This intervention will significantly reduce caregiver or broader family burden.
 - This intervention offers a novel mechanism of action or approach that will allow successful treatment of many patients who have failed other available treatments.
 - This intervention will have a significant impact on improving return to work and/or overall productivity.
 - There are other important benefits or disadvantages that should have an important role in judgments of the value of this intervention: _____

Contextual Considerations

Olaparib

- 10) Are any of the following contextual considerations important in assessing olaparib’s long-term value for money in patients with recurrent BRCA-mutated disease? (yes, no, uncertain)
- This intervention is 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.
 - This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
 - This intervention is the first to offer any improvement for patients with this condition.
 - Compared to standard chemotherapy (or PLD+C) there is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - Compared to standard chemotherapy, there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.
- 11) Are any of the following contextual considerations important in assessing olaparib’s long-term value for money in patients with platinum-sensitive disease who are eligible for maintenance therapy? (yes, no, uncertain)
- This intervention is 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.
 - This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
 - This intervention is the first to offer any improvement for patients with this condition.
 - Compared to surveillance with no maintenance chemotherapy, there is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - Compared to surveillance with no maintenance chemotherapy, there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

Rucaparib

- 12) Are any of the following contextual considerations important in assessing rucaparib's long-term value for money in patients with recurrent BRCA-mutated disease? (yes, no, uncertain)
- a. This intervention is 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. This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
 - c. This intervention is the first to offer any improvement for patients with this condition.
 - d. Compared to standard chemotherapy (or PLD+C) there is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - e. Compared to standard chemotherapy, there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - f. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

Niraparib

- 13) Are any of the following contextual considerations important in assessing niraparib's long-term value for money in patients with platinum-sensitive disease who are eligible for maintenance therapy? (yes, no, uncertain)
- a. This intervention is 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. This intervention is intended for the care of individuals with a condition that represents a particularly high lifetime burden of illness.
 - c. This intervention is the first to offer any improvement for patients with this condition.
 - d. Compared to surveillance with no maintenance chemotherapy, there is significant uncertainty about the long-term risk of serious side effects of this intervention.
 - e. Compared to surveillance with no maintenance chemotherapy, there is significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
 - f. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: _____.

