pCODR EXPERT REVIEW COMMITTEE (pERC)
FINAL RECOMMENDATION

The pCODR Provincial Advisory Group (PAG), had submitted a Request for Advice (RFA) question to pERC regarding a clinical issue for this recommendation on April 18, 2017. The revised recommendation issued on June 29, 2017 supersedes the recommendation below with respect to the RFA question. As the question was clinical, this revision does not address cost-effectiveness, patient values or adoption feasibility. Please see the RFA: Inlyta for Metastatic Renal Cell Carcinoma details page for more information: https://www.cadth.ca/rfa-inlyta-metastatic-renal-cell-carcinoma

The pan-Canadian Oncology Drug Review (pCODR) was established by Canada's provincial and territorial Ministries of Health (with the exception of Quebec) to assess cancer drug therapies and make recommendations to guide drug-funding decisions. The pCODR process brings consistency and clarity to the cancer drug assessment process by looking at clinical evidence, cost-effectiveness and patient perspectives.

pERC Final Recommendation
This pERC Final Recommendation is based on a reconsideration of the Initial Recommendation and feedback from eligible stakeholders. This pERC Final Recommendation supersedes the pERC Initial Recommendation.

Drug: Axitinib (Inlyta) **Submittter's Funding Request:** For the treatment of patients with metastatic renal cell carcinoma (RCC) of clear cell histology after failure of prior systemic therapy with either a cytokine or the VEGFR-TKI sunitinib.	
Submitted By: Pfizer Canada Inc.	**Manufactured By:** Pfizer Canada Inc.
NOC Date: July 12, 2012	**Submission Date:** August 16, 2012
Initial Recommendation: January 14, 2013	**Final Recommendation:** March 7, 2013

pERC RECOMMENDATION	The pCODR Expert Review Committee (pERC) recommends funding axitinib (Inlyta) as a second-line treatment for patients with metastatic clear cell renal carcinoma who, based on the mutual assessment of the treating physician and the patient, are unable to tolerate ongoing use of an effective dose of everolimus or who have a contraindication to everolimus. Funding in a broader patient population was not recommended because there is too much uncertainty that the effectiveness of axitinib is similar to everolimus, due to the lack of direct evidence from randomized comparative trials; however, there is a need for other options amongst patients who are either unable to tolerate or who have a contraindication to everolimus. Therefore, while current evidence is insufficient to recommend funding axitinib broadly, pERC considered that there is a need for axitinib in the subgroup of patients defined above and that this would align with patient values. This recommendation assumes similar pricing of standard dosing of the two therapies. pERC did not recommend axitinib as an alternative to everolimus or as a third-line option for patients whose disease progresses while receiving everolimus because there was insufficient clinical trial evidence to support these options.
POTENTIAL NEXT STEPS FOR STAKEHOLDERS	No next steps for stakeholders were identified by pERC

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SUMMARY OF pERC DELIBERATIONS

pERC noted that the current standard of care and most relevant comparator in the second-line treatment of metastatic renal cell carcinoma is everolimus. However, the one randomized controlled trial included in the pCODR systematic review compared axitinib with sorafenib in the second-line setting (AXIS study, Rini et al 2011). pERC noted that sorafenib has regulatory approval in Canada for use in patients who have failed or are intolerant to prior systemic therapy. pERC discussed that there are only data to support the use of sorafenib after cytokine therapy and that cytokine therapy is rarely used in the first-line setting anymore. Cytokine therapy has been replaced by sunitinib, therefore, pERC considered that sorafenib now has limited relevance as a comparator for axitinib. As a result, pERC encountered considerable uncertainty when trying to determine the relative effectiveness and safety of axitinib compared to everolimus.

pERC's Deliberative Framework for drug funding recommendations focuses on four main criteria:

CLINICAL BENEFIT	PATIENT-BASED VALUES
ECONOMIC EVALUATION	ADOPTION FEASIBILITY

pERC considered overall results from the AXIS study, which demonstrated that there is a statistically significant improvement in median progression-free survival for axitinib compared to sorafenib (6.7 versus 4.7 months, HR=0.665, 95% CI: 0.544 to 0.812, P < 0.001). pERC also noted that a similar but smaller effect was observed in the pre-specified subgroup of patients who had prior treatment with sunitinib, which is most clinically relevant in the Canadian setting (HR=0.74, 95% CI: 0.573 to 0.958, P=0.0107, median PFS 4.8 versus 3.4 months). pERC considered that this demonstrated that there is a biologic effect of axitinib in patients with metastatic renal cell carcinoma and a clinical benefit over sorafenib. However, pERC was uncertain how axitinib compared with everolimus. pERC also discussed unpublished indirect comparisons that had been conducted by the manufacturer but had concerns that interpretations based on cross-trial comparisons are uncertain regarding both the magnitude and direction of benefit. Given this uncertainty, pERC did not support funding axitinib as a second-line treatment option for all patients with metastatic renal cell carcinoma. However, pERC discussed that for a small, defined subset of patients, axitinib may meet a need for an effective treatment option. Upon reconsideration of the pERC Initial Recommendation, the Committee discussed feedback from the manufacturer relating to the analysis and conclusions of the submitted indirect comparison. pERC was unable to draw meaningful conclusions based on the results of the indirect comparison because they had methodological concerns that the results were not valid when taking into consideration the differences in study patient populations.

pERC discussed the safety of axitinib compared with sorafenib in the context of the AXIS trial. It was noted that the side effect profile of axitinib appeared consistent with its mechanism of action as a tyrosine kinase inhibitor. pERC also noted that these side effects appeared to differ from those associated with mTOR inhibitors such as everolimus. In reflecting on experience in current clinical practice, pERC noted that everolimus may not be an option for all patients, e.g., those with poor lung function. Additionally, some patients with metastatic renal cell carcinoma experience pneumonitis while on everolimus therapy, which requires discontinuing the treatment. Therefore, pERC considered that making axitinib available as an option for those patients who have intolerance to or a contraindication to everolimus would align with patient values of having more treatment options for patients with poor lung function or who had experienced serious toxicities with everolimus. Upon reconsideration of the pERC Initial Recommendation, the Committee discussed feedback from the manufacturer and patient advocacy group that axitinib should be funded as an alternative to everolimus for all patients. pERC reiterated that there is insufficient evidence evaluating axitinib relative to everolimus to support this recommendation. However, recognizing that for some patients, everolimus is not an option and that these patients have a specific clinical need for another treatment option, pERC considered it reasonable to provide this patient population with access to axitinib.

pERC discussed how intolerance to everolimus could best be defined for funding purposes and how patient care could be impacted by the definition of intolerance. pERC noted that it is important that the determination of intolerance to everolimus be based on the assessment of the treating physician, taking

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into consideration the concerns of the patient. Upon reconsideration of the pERC Initial Recommendation ,the Committee discussed feedback from the patient advocacy group reporting concerns that the definition of intolerance would lead to access delays for patients needing axitinib therapy. pERC noted that in recommending that intolerance to everolimus be based on a mutual assessment by the treating physician and patient, pERC agrees that administrative issues regarding the assessment of intolerance should not be allowed to impact access to appropriate treatment options.

pERC deliberated upon the potential use of axitinib in a first-line population or in patients whose disease progresses while taking everolimus. It was noted that there were no randomized controlled trials evaluating axitinib in these settings. In addition, pERC discussed input from the Provincial Advisory Group that sequential use of axitinib may impact adoption feasibility by increasing the budget impact of axitinib.

pERC also deliberated upon the economic evaluation submitted for axitinib and the critique provided by the pCODR Economic Guidance Panel. pERC discussed the limitations associated with the indirect comparisons that were submitted, comparing axitinib with everolimus. pERC noted that at the Health Canada recommended dose of 5 mg twice daily, the price of axitinib is similar to the price of the Health Canada recommended dose of everolimus (10 mg daily). However, pERC noted that if alternative doses are used, the cost of axitinib may be incrementally higher than the cost of everolimus, e.g. if a higher dose of axitinib were used, as was done in a large proportion of patients in the AXIS study. pERC also noted that costs other than the price of axitinib were not reported in the economic evaluation, which creates uncertainty around the total costs associated with axitinib treatment.

EVIDENCE IN BRIEF

pERC deliberated upon:

- a pCODR systematic review
- other literature in the Clinical Guidance Report providing clinical context
- an evaluation of the manufacturer's economic model and budget impact analysis
- guidance from pCODR clinical and economic review panels
- input from one patient advocacy group (Kidney Cancer Canada)
- input from pCODR's Provincial Advisory Group.

Feedback on the pERC Initial Recommendation was also provided by:

- input from pCODR's Provincial Advisory Group.
- one patient advocacy group (Kidney Cancer Canada)
- the Submitter (Pfizer Canada Inc.)

The pERC Initial Recommendation was to recommend funding axitinib (Inlyta) as a second-line treatment in patients with metastatic clear cell renal carcinoma who, based on the mutual assessment of the treating physician and the patient, are unable to tolerate ongoing use of an effective dose of everolimus or who have a contraindication to everolimus. Feedback on the pERC Initial Recommendation indicated that the manufacturer and patient advocacy group disagreed with the initial recommendation and the pCODR's Provincial Advisory Group agreed in part with the initial recommendation.

OVERALL CLINICAL BENEFIT

pCODR review scope

The pCODR review evaluated the efficacy and safety of axitinib on patient outcomes compared to standard therapies in the second line treatment of patients with advanced or metastatic renal cell carcinoma after failure of prior systemic therapy.

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Studies included: one study comparing axitinib with sorafenib

The pCODR systematic review included one study, AXIS (Rini et al 2011), an international, multi-centre, open-label randomized controlled trial that compared the efficacy and safety of axitinib to sorafenib in the second-line setting.

The pCODR review also provided contextual information on relevant comparators including everolimus (RECORD-1 study, Motzer et al 2008 and Motzer et al 2010), temsirolimus (INTORSECT study) and an analysis of the submitted indirect comparison of everolimus and axitinib. The RECORD-1 study was a double blind randomized controlled trial, comparing everolimus to placebo. The information summarized on AXIS and RECORD-1, highlighted the differences between the two trials and how this may affect the interpretation of an indirect comparison. pERC discussed these limitations and had concerns that interpretations based on cross-trial comparisons are uncertain regarding both the magnitude and direction of benefit and did not consider them sufficient to determine the overall clinical benefit of axitinib compared with everolimus. Upon reconsideration of the pERC Initial Recommendation, the Committee discussed feedback from the manufacturer relating to the analysis and conclusions of the submitted indirect comparison. pERC was unable to draw meaningful conclusions based on the results of the indirect comparison because they had methodological concerns that the results were not valid when taking into consideration the differences in study patient populations.

Patient populations: majority of patients received prior sunitinib and had lung metastases

The AXIS study included only patients with clear cell renal carcinoma and evidence of metastatic disease. Patients had an ECOG performance status of 0 or 1.

The majority of patients, 54%, had received prior sunitinib as compared to other first line treatments (cytokines, bevacizumab and temsirolimus in 35%, 8% and 3% of patients respectively). pERC considered that this reflected clinical practice in Canada and that patients who had received prior sunitinib were the most relevant patient population. This was a very different study population compared with the RECORD-1 study, which was included in the indirect comparison and evaluated everolimus compared with placebo. In RECORD-1, patients and received multiple prior treatments and may have been more refractory to treatment than those in the AXIS study.

Approximately 75% of patients in the AXIS study had lung metastases. pERC noted that in clinical practice, patients with compromised lung functioning would be less likely to be candidates for everolimus and may need another treatment option.

Key efficacy results: improved progression-free survival compared with sorafenib

The primary endpoint in the AXIS study was progression-free survival, as assessed by a blinded independent radiology committee. Other key efficacy outcomes deliberated upon by pERC included overall survival.

pERC discussed that a statistically-significant improvement in median progression-free survival was observed with axitinib compared to sorafenib in the overall study population [6.7 versus 4.7 months, hazard ratio (HR) 0.665, 95% CI: 0.544-0.812, P<0.0001]. In the pre-specified subgroup of patients who had received prior sunitinb, a similar but smaller improvement in median progression free survival was also observed for axitinib compared to sorafenib (4.8 versus 3.4 months, HR=0.74,95% CI 0.573 to 0.958, P=0.0107). pERC noted that the results in patients previously treated with sunitinib were the most relevant to the Canadian population. pERC further deliberated upon these results and considered that the data demonstrated that axitinib is an active drug in this population. However, pERC was challenged in determining how axitinib compared with everolimus, which is the most clinically relevant comparator.

pERC also noted that median overall survival was similar between axitinib and sorafenib (20.1 versus 19.2 months, HR=0.969, 95% CI: 0.800 to 1.174, P=0.374).

Quality of life: similar between axitinib and sorafenib

In the AXIS study, symptom improvements and quality of life were measured using the Fact-Kidney Symptom Index (FKSI). The FKSI includes 15 questions and a 9-question subscale that measures symptoms of advanced renal cell carcinoma including lack of energy, pain, weight loss, fatigue, shortness of breath, time to deterioration. No difference in the overall mean FKSI-15 scores between axitinib and sorafenib were reported over time. pERC discussed these results and noted that quality of life was valued by patients based on input received from Kidney Cancer Canada.

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Safety: adverse events consistent with mechanism of action and manageable

In the AXIS study, the proportions of patients with fatal and non-fatal serious adverse events were similar between the axitinib and sorafenib groups. Diarrhoea, hypertension and fatigue were the most commonly reported adverse events for both axitinib and sorafenib. The adverse events were generally mild or moderate in severity and manageable through dose interruptions, dose reductions, and/or standard medical management. Compared with sorafenib, more patients receiving axitinib experienced dysphonia, nausea, hypothyroidism and hypertension and fewer patients experienced hand-foot syndrome and rash. pERC noted that this side effect profile was consistent with the expected mechanism of action of a tyrosine kinase inhibitor and different from that of a mTOR inhibitor such as everolimus. pERC discussed the challenges of comparing the safety of axitinib with everolimus based on cross-trial comparisons. However, pERC noted that in clinical practice, patients with poor lung function would be less likely to receive everolimus because of concerns about drug-related lung toxicity and that axitinib may be an option for these patients.

Limitations: No direct comparison with everolimus and no ongoing trials

The main limitation identified by pERC in the evidence for axitinib is that there are no randomized controlled trials directly comparing it with everolimus, the current standard of care in the second line setting. pERC also noted that there are no planned or ongoing trials that will compare axitinib with everolimus. pERC also discussed the limitations of conducting an indirect treatment comparison between axitinib and everolimus, given the available clinical evidence, and the resulting challenges in conducting a cost-effectiveness analysis.

Comparator Information: Uncertainty in results of indirect comparisons

In the absence of trials directly comparing axitinib with everolimus, pERC discussed contextual information provided in the pCODR Clinical Guidance Report on relevant comparators and the limitations of doing an indirect comparison between axitinib and everolimus. pERC noted that because of differences in the study populations and the study designs of the RECORD-1 study and the AXIS study and the lack of a common control group between the studies, the results of the indirect comparison would have a number of limitations and be extremely uncertain.

Need: alternatives for patients intolerant to or with contraindications to everolimus

Currently kidney cancer accounts for approximately 3% of all cancers in Canada with approximately 90-95% being clear cell renal carcinoma. The estimated five-year survival across all stages is 67% but the prognosis for patients with metastatic disease remains poor with only a very few surviving longer than five years. Despite advances in treatment options, none of the currently available systemic treatment options for metastatic RCC (including targeted therapy, immunotherapy, or conventional chemotherapy) is considered curative and all of these therapies are associated with various degrees of side effects.

pERC discussed that everolimus is currently the standard of care in the second-line setting and that there may be patients who have a contraindication to or who are intolerant to everolimus who are in need of another treatment option, e.g. patients with poor lung function. pERC noted that in clinical practice there are often patients who experience serious toxicity with everolimus and who, currently, would not have any other treatment options. Upon reconsideration of the pERC Initial Recommendation, the Committee discussed feedback from the manufacturer and patient advocacy group that axitinib should be funded as an alternative to everolimus for all patients. pERC reiterated that there is insufficient evidence evaluating axitinib relative to everolimus to make this recommendation. However, recognizing that for some patients, everolimus is not an option and that these patients have a specific clinical need for another treatment option, pERC considered it reasonable to provide this small patient population with access to axitinib. pERC also discussed feedback from the patient advocacy group reporting concerns that the definition of intolerance would lead to delays in getting access to axitinib. pERC noted that recommending that intolerance to everolimus be based on a mutual assessment by the treating physician and patient may reduce administrative issues regarding the assessment of intolerance and access to appropriate treatment options. Upon reconsideration of the pERC Initial Recommendation, pERC also noted patient advocacy group concerns that patients found to be intolerant to everolimus and switched to axitinib may be classified as having moved to a third line of therapy. pERC discussed that treating physicians would not likely regard intolerance, for example due to pneumonitis, as equivalent to failing a line of therapy due to disease progression.

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PATIENT-BASED VALUES

Values of patients with metastatic renal cell carcinoma: maintaining quality of life and disease stability

pERC considered patient advocacy group input highlighting that patients with metastatic renal cell carcinoma experience many symptoms, including shortness of breath, cough, fatigue, severe abdominal or back pain, bone pain and bone fractures. Patient advocacy group input expressed a desire for choice in second-line therapy so that patients can continue to manage their disease and side effects while maintaining their quality of life. From a patient perspective, prolonging progression-free survival and allowing for extended control of disease (e.g., tumor shrinkage or stability) are important treatment goals.

Patient values on treatment: alternative treatment option and willing to accept side effects

Patient advocacy group input indicated that everolimus is the only second-line treatment option funded in Canada and that for some patients, the side effects of everolimus could have a significant impact on quality of life and daily activities. Patient advocacy group input also noted that for patients with lung impairment, everolimus is not an option and an alternate treatment is required. pERC discussed this and noted that for patients intolerant to or with a contraindication to everolimus, there are no other second-line treatment options. Therefore, pERC considered that providing axitinib as an option for this small subset of patients would align with patient values.

Patient advocacy group input reported that of the small number of patients who had experience taking axitinib, many were willing to accept the associated side effects and the majority considered their quality of life while taking axitinib to be moderate to high. Patients indicated that they are aware that all treatments for advanced cancer have risks associated with them and that they are willing to tolerate moderate to significant side effects during their treatment. pERC noted this and considered that the side effect profile of axitinib would likely be acceptable to patients and that the side effects appear to be manageable in clinical practice through dose adjustments and interruptions.

ECONOMIC EVALUATION

Economic model submitted: cost minimization

The pCODR Economic Guidance Panel assessed a cost minimization analysis provided by the submitter, comparing axitinib with everolimus. Because of the lack of head-to-head trials comparing these two drugs, the cost minimization analysis was based on an indirect treatment comparison and assumed similar efficacy and safety for axitinib and everolimus.

pERC discussed the appropriateness of this approach and found that there were considerable challenges in interpreting the cross-trial comparisons and serious limitations with the indirect treatment comparisons. However, pERC noted that these limitations would have also existed in a cost-effectiveness analysis that was informed by the indirect treatment comparison. Therefore, while not ideal, in these circumstances, pERC considered this approach to be reasonable. It was noted that if, in future, the assumption around equal efficacy and safety between axitinib and everolimus was proven incorrect, a cost-minimization approach would no longer be valid and a standard cost effectiveness or cost-utility analysis would be required.

Basis of the economic evaluation: drug costs and indirect treatment comparison

The costs considered in the analysis included only the cost of axitinib and everolimus. pERC noted that there were likely additional costs associated with the treatment and management of these patients but was uncertain about how these costs would differ between the axitinib and everolimus groups. However, based on clinical experience managing patients with advanced cancer and the evidence for these two drugs, pERC was unable to identify any areas where costs were expected to differ substantially.

The clinical effects were based on a submitted and unpublished indirect treatment comparison that included one study comparing axitinib with sorafenib (N=723) and one study comparing everolimus with placebo (N=416). Three different analytical approaches were taken to the conduct of the indirect treatment comparison and similar results were obtained with all three approaches. However, the indirect

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treatment comparison did not include a robust analysis of potential harms. The results of the indirect treatment comparison indicated that axitinib may have greater efficacy than everolimus, however, for the purposes of the cost minimization analysis, it was assumed that efficacy was similar between the two drugs. pERC discussed this and noted that the manufacturer had made a conservative assumption in the cost-minimization analysis.

Although a conservative assumption was made in the cost-minimization analysis, pERC could not recommend axitinib for patients who can receive everolimus because of the considerable uncertainty around the assumption of similar efficacy and safety between axitinib and everolimus.

Drug costs: alternate doses may increase drug costs of axitinib relative to everolimus

Axitinib costs $18.60 per 1 mg tablet and $93.00 per 5 mg tablet, at the list price. At the recommended dose of 5 mg twice daily, the average cost per day is $186.00 and the average cost per 30-day course is $5,580. Everolimus costs $186.00 per 5 mg and 10 mg tablets, at the list price. At the recommended dose of 10 mg daily, the average cost per day is $186.00 and the average cost per 30-day course is $5,580.

Although the prices of axitinib and everolimus are the same at the Health Canada recommended daily doses, if higher doses of axitinib are used, the cost of axitinib may be greater than the cost of everolimus. pERC noted that the majority of patients receiving axitinib in the AXIS study required dosage adjustments and a large proportion of patients received a dose higher than the recommended 10 mg per day. The submitted economic evaluation did not consider the possibility of axitinib dose adjustments; therefore, the pCODR Economic Guidance Panel conducted a reanalysis using alternative doses of axitinib. This resulted in incremental costs of between $0 and $335 for axitinib versus everolimus. pERC considered that the impact of axitinib dose adjustments would need to be considered in the budget impact analyses of axitinib.

ADOPTION FEASIBILITY

Considerations for implementation and budget impact: additional cost of treating patients intolerant to or with a contraindication to everolimus

pERC noted that the submitted budget impact analysis addressed the use of axitinib in patients currently receiving everolimus but not the use of axitinib in patients who are intolerant to or contraindicated to everolimus. pERC noted that the use of axitinib in this latter population would result in additional costs, since these patients do not currently have treatment options available to them. pERC further noted that the potential for dose adjustments will need to be considered by provinces as this could affect the incremental cost of axitinib relative to everolimus. pCODR's Provincial Advisory Group input also identified sequential use of axitinib as a potential factor that could further increase budget impact. pERC considered that there is no clinical trial evidence to support the use of axitinib in the first-line or in patients whose disease progresses while receiving everolimus.

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DRUG AND CONDITION INFORMATION

Drug Information	• Multi-target tyrosine kinase inhibitor • 1 mg and 5 mg reviewed by pCODR • Recommended dosage of 5 mg orally twice daily
Cancer Treated	• Advanced or metastatic renal cell carcinoma with clear-cell histology after failure of prior systemic therapy with either a cytokine or the VEGFR-TKI, sunitinib
Burden of Illness	• 5600 new cases (all stages) will be diagnosed in 2012 with approximately 1700 deaths reported. • Estimated five-year survival across all stages is 67% but prognosis for patients with metastatic disease remains poor with very few surviving over 5 years • Males are more frequently affected with a predominance of 1.8 to 1.
Current Standard Treatment	• In the first line setting, sunitinib is the current standard of care and more recently pazopanib, both VEGFR inhibitors • Everolimus, an oral mTOR inhibitor is considered standard of care in second line setting. Sorafenib is also a treatment option in the second line setting, after previous cytokine therapy
Limitations of Current Therapy	• None of the currently available treatment options are considered curative and all therapies are associated with various degrees of side effects • Ongoing need for better therapy options in the treatment of metastatic RCC, which improve efficacy outcomes, reduce toxicity or both

ABOUT THIS RECOMMENDATION

The pCODR Expert Review Committee (pERC)

Recommendations are made by the pCODR Expert Review Committee following the pERC Deliberative Framework. pERC members and their roles are as follows:

Dr. Anthony Fields, Oncologist (Chair)
Dr. Maureen Trudeau, Oncologist (Vice-Chair)
Dr. Chaim Bell, Economist
Dr. Scott Berry, Oncologist
Bryson Brown, Patient Member
Mario de Lemos, Pharmacist
Dr. Sunil Desai, Oncologist
Mike Doyle, Economist;
Dr. Bill Evans, Oncologist
Dr. Allan Grill, Family Physician
Dr. Paul Hoskins, Oncologist
Danica Lister, Pharmacist
Carole McMahon, Patient Member Alternate
Jo Nanson, Patient Member
Dr. Peter Venner, Oncologist
Dr. Tallal Younis, Oncologist

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All members participated in deliberations and voting on the initial recommendation except:

- Dr. Peter Venner who was excluded from deliberations and voting due to a conflict of interest
- Dr. Allan Grill and Dr. Chaim Bell who were absent from the meeting
- Carole McMahon who did not vote due to her role as a patient member alternate

All members participated in deliberations and voting on the final recommendation except:

- Jo Nanson and Dr. Bill Evans who were absent from the meeting
- Dr. Peter Venner who was excluded from deliberations and voting due to a conflict of interest

Avoidance of conflicts of interest

All members of the pCODR Expert Review Committee must comply with the *pCODR Conflict of Interest Guidelines*; individual conflict of interest statements for each member are posted on the pCODR website and pERC members have an obligation to disclose conflicts on an ongoing basis. For the review of axitinib (Inlyta) for mRCC, through their declarations, eight members had a real, potential or perceived conflict and based on application of the *pCODR Conflict of Interest Guidelines*, one of these members was excluded from voting.

Information sources used

The pCODR Expert Review Committee is provided with a *pCODR Clinical Guidance Report* and a *pCODR Economic Guidance Report*, which include a summary of patient advocacy group and Provincial Advisory Group input, as well as original patient advocacy group input submissions to inform their deliberations. pCODR guidance reports are developed following the pCODR review process and are posted on the pCODR website. Please refer to the pCODR guidance reports for more detail on their content.

Consulting publicly disclosed information

pCODR considers it essential that pERC recommendations be based on information that may be publicly disclosed. All information provided to the pCODR Expert Review Committee for its deliberations was handled in accordance with the *pCODR Disclosure of Information Guidelines*. There was no non-disclosable information in this recommendation document.

Use of this recommendation

This recommendation from the pCODR Expert Review Committee (pERC) is not intended as a substitute for professional advice, but rather to help Canadian health systems leaders and policymakers make well-informed decisions and improve the quality of health care services. While patients and others may use this Recommendation, it is for informational and educational purposes only, and should not be used as a substitute for the application of clinical judgment respecting the care of a particular patient, for professional judgment in any decision-making process, or for professional medical advice.

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